

June 29, 2009

Barbara O. Schneeman, Ph.D.
Director Office of Nutrition, Labeling, and
Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
Rockville, MD 20740

Dear Dr. Schneeman:

The Center for Science in the Public Interest (CSPI) requests that the Food and Drug Administration (FDA) take enforcement action against Bayer HealthCare LLC. Bayer's "One A Day Men's Health Formula" multivitamin is an unapproved drug in violation of §§ 201(g) and 505(a) of the Federal Food, Drug, and Cosmetic Act (FDCA). Moreover, Bayer's claims are false and misleading which render the product misbranded under § 403(r)(1)(B) of the Act. Bayer also makes deceptive claims on labels (and labeling) of its One A Day Men's 50+ Advantage multivitamin.

On June 18, 2009, CSPI filed a complaint with the Federal Trade Commission (FTC) about misleading advertising claims Bayer has been making for those products (Attachment A). Because Bayer's labels are an important part of a large-scale campaign to deceive consumers, we urge you to coordinate with the FTC and take prompt action to halt both the labeling and advertising claims. (CSPI also notified Bayer of our intent to file a lawsuit, unless the company stopped those claims -- Attachment B).

As a result of these earlier CSPI actions, Bayer has stated in several media reports that the company is halting claims that its product can reduce the risk of prostate cancer.¹ A Bayer spokesperson stated: "Though the company did push selenium as an aid in cancer prevention, 'we decided to no longer utilize this language in our promotion and labeling of our products.'"²

The FDA, however, should seize existing stockpiles of the Bayer products containing the cancer prevention claim, under §304 (a)(1)(B) of the FDCA, and work with state enforcement officials to see that such products are immediately removed by retailers from store shelves. As explained in section III-B below, cancer prevention claims on existing stockpiles of Bayer's "One A Day Men's Health Formula" multivitamin are dangerous to the health of men suffering

¹ FDA Looms Large as Bayer Surrenders One a Day Selenium Prostate Claims, *The Tan Sheet*, June 29, 2009, Vol. 17, Number 26.

² Statement of Tricia McKernan on behalf of Bayer HealthCare, <http://www.tampabay.com/features/consumer/article1013770.ece>, accessed June 27, 2009.

from prostate cancer and may increase the risk of diabetes and hypertension. Given that the misbranded articles are “dangerous to health,” and contain label claims that are misleading in a material respect that can lead to injury, FDA should use its seizure authority to immediately remove those products from the marketplace, *Id.*

Furthermore, Bayer has not promised to remove other false and misleading claims from its products’ labels, such as “to support prostate health.” As explained in Section III below, such claims are not supported by competent and reliable scientific evidence and should be halted. Thus despite Bayer’s recent announcements in the media, CSPI considers this case far from closed and requests that the FDA take prompt enforcement action.

I. The Bayer Label Exceeds the Parameters of the FDA’s Qualified Health Claim Authorization Letter Issued on August 28, 2003 and Does Not Meet the Requirements Set Forth in FDA’s June 19, 2009 Authorization Letter

A. Violations of FDA’s 2003 Authorization Letter

On April 28, 2003,³ FDA issued a letter permitting a qualified health claim for selenium and the prevention of cancer, but allowed the use of only the terms “certain cancers,” “certain forms of cancer,” and “anti-carcinogenic effects.” The Agency did not permit the use of “prostate cancer” in the qualified health claim.⁴ FDA stated that the “evidence is limited and not conclusive,” indicating that the claim has a low level of scientific support.

Nevertheless, the label of Men’s Health Formula deliberately misleads consumers by failing to use only the prescribed language that FDA has set forth as a condition for utilizing the qualified health claim for selenium. By surrounding the approved qualified health claim language with the claim “supports prostate health,” as well as expressly mentioning “prostate cancer” by name, Bayer ignores the FDA’s requirement that this particular qualified health claim not identify any specific forms of cancer for which selenium may have preventive benefits.

The label for One A Day Men’s Health Formula, for example, states:

Did you know that prostate cancer is the most frequently diagnosed cancer in men and that emerging research suggests that Selenium may reduce the risk of prostate cancer? One A Day’s Men’s Health Formula is a complete multivitamin plus key nutrients including Selenium to support a healthy prostate.⁵ *Selenium may reduce the risk of certain cancers. Some scientific evidence suggests that consumption of Selenium may reduce the risk of certain forms of cancer. However, FDA has*

³ Selenium and Certain Cancers (Qualified Health Claim: Final Decision Letter) (Docket No. 02P-0457) (Apr. 28, 2003) available at <http://www.fda.gov/FoodLabelingNutrition/LabelClaims/QualifiedHealthClaims/ucm072>.

⁴ *Id.* at 9-10.

⁵ Cancer aside, there is inadequate evidence to support a benefit of selenium with regard to *any* aspect of “a healthy prostate,” and the FDA should halt all “healthy prostate” claims on Bayer and other selenium-containing products. See section III below.

determined that this evidence is limited and not conclusive. [Only the italicized sentences are authorized in the qualified health claim.] (Attachment C).

Thus, the authorized claim is buried in the kind of language FDA sought to prevent companies from using. Accordingly, the product constitutes an unapproved drug and is misbranded.

B. Violations of FDA's 2009 Authorization Letter

Furthermore, the Bayer label does not meet the requirements for a qualified health claim for prostate cancer under FDA's recently announced policy. In a letter dated June 19, 2009, FDA revised its policy on claims for "certain cancers," concluding that "the claim 'selenium may reduce the risk of certain cancers' is incomplete and misleading because it fails to reveal the individual cancer(s) that selenium may have an effect on."⁶ FDA then concluded that "there is very limited credible evidence for a relationship between selenium supplements and reduced risk of prostate cancer. . . . FDA concludes that it is highly unlikely that selenium supplements reduce the risk of prostate cancer. . . ."⁷

FDA stated it will allow the following qualified health claim:

Two weak studies suggest that selenium intake may reduce the risk of prostate cancer. However, four stronger studies and three weak studies showed no reduction in risk. Based on these studies, FDA concludes that it is highly unlikely that selenium supplements reduce the risk of prostate cancer.⁸

Significantly, FDA said it would allow this claim only for supplements containing the selenomethionine form of selenium.⁹ One A Day contains sodium selenite. Thus, Bayer is prohibited from making the qualified health claim even under FDA's latest policy statement.

II. Bayer's Web Site Makes Health Claims Not Permitted by the FDA's 2003 or 2009 Authorization Letters

Bayer's website,¹⁰ which is referenced on the Men's Health Formula label, further attempts to cement the link in the consumer's mind between selenium and the reduction of prostate cancer. FDA has concluded that a reference on a product label to additional material on

⁶ Letter to Jonathan W. Emord, Esq., from Barbara O. Schneeman, Ph.D., Director, Office of Nutrition, Labeling and Dietary Supplements re: Qualified Health Claim Petition – selenium and a reduced risk of site-specific cancers (FDA-2008-Q-0323) (June 19, 2009) at 7 and n. 18.

⁷ *Id.* at 34.

⁸ *Id.* at 37.

⁹ *Id.* at 35.

¹⁰ <http://www.oneaday.com> (accessed June 19, 2009).

a company's Web site causes the Internet material to be "labeling" subject to FDA's jurisdiction.¹¹

Bayer states:

One A Day Men's Presents Major League Baseball Strikeout Prostate Cancer Challenge.

One A Day and MLB are teaming up to support the Prostate Cancer Foundation.

1 in 6 men face prostate cancer and that is why One A Day and MLB will donate \$10 for every strikeout this season to support prostate health awareness and research.

(Attachment D)¹²

Another page states:

Prostate cancer is the most frequently diagnosed non-skin cancer in men, and emerging research suggests Selenium may reduce the risk of prostate cancer. One a Day Men's Health Formula is a complete multivitamin plus key nutrients to support a healthy heart and Selenium to support a healthy prostate.¹³ (Attachment E)

The above claims cause the product to be an unapproved drug, as well as misbranded under Section 403(1)(B).¹⁴

III. Bayer's Claim that One A Day Men's Health Formula and One A Day Men's 50+ Advantage "Supports Prostate Health" is False and Misleading

Bayer also makes false and misleading claims¹⁵ on the labels of its One A Day Men's Formula and One A Day Men's 50+ Advantage (Attachment F). The FDA should require Bayer

¹¹ Warning letter to Ken Powell, Chairman of the Board, General Mills from W. Charles Becoat, Director, Minneapolis District, FDA (May 5, 2009); Warning letter to Robert Hawthorne, President Ocean Spray Cranberries from Gail T. Costello, District Director New England District Office, FDA (Jan. 19, 2001).

¹² http://www.oneaday.com/strikeout_challenge.html (accessed June 19, 2009).

¹³ <http://www.oneaday.com/mens.html> (accessed June 19, 2009). Subsequently, the references to prostate cancer were removed from Bayer's website for Men's Health Formula on this particular page. The Strike Out Prostate Cancer Challenge remains.

¹⁴ Even if Bayer replaces all of its prostate cancer claims on its products with "healthy prostate" claims, we suspect that many men would assume that "healthy" in the context of the prostate refers to prostate cancer, the most common cancer in men.

¹⁵ Although Bayer uses wording arguably associated with structure/function claims in its statement "supports prostate health," the statement should be construed as an impermissible implied disease prevention claim. In the Preamble to the final rule on structure/function claims for dietary supplements, FDA determined that claims such as

to remove the claim “supports prostate health” because it is not supported by competent and reliable evidence as required by FDA’s Guidance on substantiation for claims made under § 403(r)(6), and hence is false and misleading under section 403(a) of the FDCA.

Under the competent and reliable evidence standard, “[c]onflicting or inconsistent results raise serious questions as to whether a particular claim is substantiated.”¹⁶ A key factor to consider is “if multiple studies exist, what do most studies suggest or find? Does the totality of the evidence agree with the claim(s)?”¹⁷ Unless the manufacturer can offer a plausible explanation to explain the disparate results, the available evidence is most likely not adequate to substantiate the claim.¹⁸

A. Experts Have Concluded that Selenium Does Not Prevent Prostate Cancer

Significantly, a major study released after the issuance of FDA’s 2003 letter indicates that there is inadequate support for the prostate-cancer claim. The Selenium and Vitamin E Cancer Prevention Trial (SELECT), funded by the National Institutes of Health -- the only randomized controlled trial investigating specifically whether selenium

“Maintains normal urine flow in men over 50” or claims related to benign prostatic hyperthrophy (BPH) are disease claims. FDA explained that:

‘Helps to maintain normal urine flow in men over 50 years of age’ . . . is an implied disease claim because . . . the average or ‘normal’ state in men over 50 years old is diminishing urine flow, in most cases due to BBH, so that the apparent ‘maintenance’ really represents a claim of improvement (treatment.)

FDA also expressed concern that claims to treat or prevent BPH should be treated as disease claims “because failure to obtain effective treatment can cause significant or permanent harm.” FDA, *Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, Final Rule*, 65 Fed. Reg. 1000, 1021 (Jan. 6, 2000).

Most notably, the FDA did not provide any example of a permissible structure/function claim for “prostate health.” *Id.*

Furthermore, both FDA and industry studies demonstrate that consumers do not differentiate between structure/function claims and health claims. International Food Information Council. *Qualified Health Claims Consumer Research Summary Project, March 2005* at 11. Available at <http://www.ific.org/research/qualhealthclaimsres.cfm>; General Accounting Office, *Food Safety, Improvements Needed in Overseeing the Safety of Dietary Supplements and “Functional Foods,”* 23 GAO/RCED-00-156 (July 2000).

Indeed, with some simple wordsmithing, disease prevention claims requiring FDA pre-market authorization have been presented on labels as so-called structure/function claims with little to no scientific backing. Supplement manufacturers have recognized this gap in FDA policy and have enthusiastically embraced structure/function claims for marketing purposes. The FDA must stop this trend in its tracks.

¹⁶ FDA, Guidance for Industry, Substantiation for Dietary Supplement Claims Under Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act (Dec. 2008) at 16, available at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocument>.

¹⁷ *Id.* at 18.

¹⁸ *Id.*

supplementation prevents prostate cancer -- was halted in October 2008 after seven years. SELECT was a large and well-executed trial that would have picked up even a slight benefit from selenium. It found none.¹⁹ A letter from leading prostate-cancer experts to the FTC (Attachment G) states:

The seven-year Selenium and Vitamin E Cancer Prevention Trial (SELECT) produced strong evidence last October that selenium does not prevent prostate cancer in a generally healthy, heterogeneous population of men in the United States and Canada.

Thus Bayer should not be permitted to continue the claim “protects prostate health.” FDA’s prohibition of this false and misleading claim is essential to protect consumers from deception. Given the negative language in the qualified health claim that FDA recently authorized for selenium and prostate cancer, it is likely that many companies will opt for a structure/function claim. A spokesman for the Natural Products Association was quoted as stating that the qualified health claims “are not very useful” and that he could not “see why anyone would want to use these claims.”²⁰ As a result, Bayer is much more likely to attempt to market its product on the basis of a structure/function claim such as “supports prostate health.” Thus to prevent consumers from being misled, it is essential that FDA halt not only the unauthorized health claim, but the “supports prostate health” claim as well.

B. Selenium Supplements May Increase the Risk of Diabetes and Hypertension, and increase the aggressiveness of prostate cancer in men with the disease.

The organizers of the SELECT study found that, while selenium supplementation was having no benefit whatsoever with respect to prostate cancer, the supplements may have increased the risk of developing diabetes. The data and safety monitoring committee had “some concern” over a nonsignificant increase in diabetes mellitus associated with selenium supplementation ($p=.08$).²¹

Furthermore, men with high levels of selenium in their blood who carry the V genotype for the enzyme manganese superoxide dismutase have a significantly increased risk for aggressive prostate cancer, according to a new study published online June 15 in the *Journal of Clinical Oncology*.²² Manganese superoxide dismutase functions as an antioxidant in nearly all cells exposed to oxygen. June M. Chan of the University of California at San Francisco and her colleagues examined the genotypes for this enzyme and blood selenium levels in 489 men with localized or locally advanced prostate cancer. The V genotype is carried by 75 percent of all men, according to Chan. “These data...indicate caution against broad use of selenium supplementation for men with prostate cancer,” the researchers concluded.

¹⁹ Journal of the American Medical Association, 301:39-51.

²⁰ Statement of Daniel Fabricant, Ph.D., Vice President of Scientific and Regulatory affairs, Natural Products Association, *quoted in* Lorraine Heller, Selenium health claims: Too qualified to qualify? Food Navigator-usa.com (June 23, 2009) available at <http://www.foodnavigator-usa.com/content/view/print/251455>.

²¹ Id.

²² <http://jco.ascopubs.org/cgi/content/abstract/JCO.2008.18.8938v1>.

Men and women with high blood selenium concentrations were more likely to be hypertensive than those with lower levels of selenium in a recent representative study of the U.S. population. A study by researchers at the Johns Hopkins University Bloomberg School of Public Health reviewed cross-sectional data for 2,638 men and women aged 40 and older from the 2003-2004 National Health and Nutrition Examination Survey (NHANES). After controlling for sex, age, race, education, body mass index, smoking, menopausal status, and use of vitamin/mineral supplements, they found that those in the top two quintiles for blood selenium levels were about 75 to 100 percent more likely to have hypertension (defined as a blood pressure of at least 140/90 or taking hypertensive medication) as those with selenium levels in the lowest quintile.

“From a clinical perspective, selenium supplements cannot currently be recommended for cardiovascular protection...Our findings call for a thorough evaluation of the risks and benefits associated with high selenium status in the United States,” the researchers concluded.²³

Those potential risks of selenium supplementation are all the more reason why Bayer should not be allowed to continue to claim that its product “supports prostate health.”²⁴

FDA’s prohibition of this false and misleading structure/function claim is essential to protecting consumers from deception. Given the negative language in the qualified health claim that FDA recently authorized for selenium and prostate cancer, it is unlikely that many companies will use the claim, but instead will opt for a structure/function claim.²⁵ As a result, Bayer is much more likely to attempt to market its product on the basis of a structure/function claim such as “supports prostate health.” Thus to prevent consumers from being misled, it is essential that FDA halt not only the unauthorized health claim, but the “supports prostate health” claim as well.

²³ Laclaustra M., et al. Serum selenium concentrations and hypertension in the US population. Circ Cardiovasc Qual Outcomes published online June 16, 2009. DOI: 10.1161/CIRCOUTCOMES.108.831552.

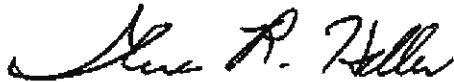
²⁴ Although FDA recently authorized a qualified health claim for selenomethionine (a type of selenium not contained in the Bayer product) and prostate cancer notwithstanding the SELECT study results, it did so under the “credible evidence” standard that applies to qualified health claims and required that the claim be accompanied by strong negative disclaimers. Under the “competent and reliable” scientific evidence standard applicable to structure/function claims, the “supports prostate health” statements cannot be made.

²⁵ See n. 18, *supra*.

IV. Conclusion

We urge the Agency to take prompt action to ensure that Bayer's One A Day Men's Health Formula is no longer marketed with unauthorized health claims and that the deceptive claim "supports prostate health" be discontinued. While Bayer has announced that it intends to cease the use of the unauthorized health claims, the FDA should seize existing stockpiles of Bayer products containing cancer prevention claims under §304 (a)(1)(B) of the FDCA, and work with state enforcement officials to see that such products are immediately removed by retailers from store shelves. The FDA should also require the company to halt the more general claims that the products support prostate health.

Respectfully Submitted,

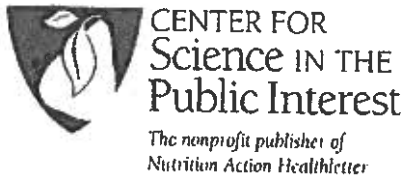


Ilene Ringel Heller
Senior Staff Attorney



David Schardt
Senior Nutritionist

cc: Vasilios Frankos, Robert J. Moore



June 18, 2009

Ms. Mary K. Engle
Associate Director
Advertising Practices
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

Dear Ms. Engle:

The Center for Science in the Public Interest (CSPI)¹ is bringing to the attention of the Federal Trade Commission the misleading and irresponsible claims Bayer Healthcare LLC ("Bayer") is making in advertisements for its two men's One A Day multivitamins ("multis").

Pursuant to Section 4(d) of the Administrative Procedure Act, 5 U.S.C. § 553(e), and 16 C.F.R. § 2.1, we request that the Federal Trade Commission halt the false and misleading claims made in advertisements by Bayer. Each advertisement constitutes a "false advertisement" as defined by Sections 12 and 15 of the Federal Trade Commission Act (FTCA), 15 U.S.C. §§ 52, 55, and hence is "unfair or deceptive" under Section 5 of the FTCA, 15 U.S.C. § 45. These advertisements also violate the FTC consent decree Bayer signed in January 2007.

The two dietary supplements are Bayer's One A Day[®] Men's 50+ Advantage multivitamin and Bayer's One A Day[®] Men's Health Formula multivitamin. Both contain 105 micrograms of the trace mineral selenium per daily dose, or about twice the Recommended Dietary Allowance (RDA), which is 55 micrograms a day for adults.²

Bayer's Dishonest Marketing Campaign

Bayer promotes in several ways the extra selenium in these men's multis for the prevention of prostate cancer: on package labels, on its website, and in television and radio advertisements. According to VMS, an advertisement monitoring service, Bayer

¹ CSPI, a non-profit consumer organization supported by approximately 900,000 members, has worked since 1971 to improve national health policies. We have been especially concerned about the effect of dietary supplement advertising on consumer health.

² Centrum Silver from Wyeth Consumer Healthcare, on the other hand, contains 55 micrograms per daily dose.

has run at least 11 different television ads and at least 9 different radio ads since 2008 linking the prevention of prostate cancer to their men's multivitamins.³

Here's a transcript of one of the radio ads:

Prostate cancer. It's an important subject. Did you know that there are more new cases of prostate cancer each year than any other cancer? And here's something else you should know. Now, there's something that you can do that may help reduce your risk. Along with your regular doctor checkups, switch to One A Day men's. A complete multivitamin plus selenium, which emerging research suggests may reduce the risk of prostate cancer. One A Day Men's. Because staying healthy is serious business.⁴

From the company website:

Did you know that 1 in 6 men will face prostate issues? Prostate cancer is the most frequently diagnosed non-skin cancer in men, and emerging research suggests Selenium may reduce the risk of prostate cancer.⁵

From the back of the package for One A Day Men's Health Formula:

Did you know that prostate cancer is the most frequently diagnosed cancer in men and that emerging research suggests Selenium may reduce the risk of prostate cancer?⁶

In fact, the most important and compelling research by far to emerge on this question, the federally funded Selenium and Vitamin E Cancer Prevention Trial (SELECT), did not find any evidence that selenium reduces the risk of prostate cancer in average, healthy men.⁷

First Trial found Selenium May Have Benefited Only a Very Small Subgroup of Men

The notion that selenium might reduce the risk of prostate cancer was inspired by the Nutritional Prevention of Cancer (NPC) trial, the first results of which were published in 1996.⁸ Although the NPC trial's primary objective was to evaluate whether selenium

³ VMS search conducted for CSPI on March 23, 2009.

⁴ "More new cases of prostate cancer each year than others," VMS ID 080422285

⁵ <http://www.oneaday.com/mens.html> (accessed June 16, 2009)

⁶ See Attachment A.

⁷ ~~The Food and Drug Administration did approve a qualified health claim in 2003 for selenium supplementation and the reduction in risk of "certain forms of cancer," but not for any specific cancer. This qualified claim must be accompanied by the statement: "However, FDA has determined that this evidence is limited and not conclusive." This statement appears on package labels of One A Day[®] Men's 50+ Advantage and One A Day[®] Men's Health Formula, but not on the One A Day websites or in other advertisements. <http://www.cfsan.fda.gov/~dms/ds-ltr35.html>~~

⁸ JAMA. 1996 Dec 25;276(24):1957-63

supplementation prevents skin cancer (it didn't), an analysis of secondary outcomes found that the men in the study who received 200 micrograms of yeast-based selenium had a significantly lower risk of developing prostate cancer over the six years of the study.

The NPC trial was the first and only randomized controlled trial in men to see such an effect from selenium. Subsequent examinations of the NPC data found that the benefits of selenium supplementation in this study were less than what they first seemed.

A 2003 analysis of the NPC data determined that the benefit of selenium supplementation for the prevention of prostate cancer was limited to a very small subgroup of men with the lowest levels of blood selenium and low baseline PSA scores.⁹

Furthermore, a 2007 analysis of the NPC data found nearly a three-fold increased risk of self-reported diabetes in the men who were assigned to take selenium and who had the highest levels of blood selenium at the start of the trial.¹⁰ In response to that finding, the American College of Physicians issued a summary for patients, stating:

Selenium supplements appear to increase the risk for diabetes. Although the findings need to be confirmed, long-term selenium supplementation should not be viewed as harmless and a possibly healthy way to prevent illness.¹¹

Larger, Second Trial of Selenium Found It Ineffective for Preventing Prostate Cancer

In 2001, the National Institutes of Health began the \$118.5 million Selenium and Vitamin E Cancer Prevention Trial (SELECT), based in large measure on the promising initial evaluation of the NPC study. The largest prostate cancer prevention study ever undertaken, SELECT was designed to see if 200 micrograms of selenium in the form of selenomethionine, or 400 IU of vitamin E, or a combination of the two could lower the risk of developing prostate cancer more than a placebo in 35,000 men in the United States, Puerto Rico, and Canada.

The SELECT trial was designed to last up to twelve years. However, in October 2008, it was abruptly terminated after seven years when the study's independent Data and Safety Monitoring Committee reviewed the SELECT data up to that point and concluded that selenium was not preventing prostate cancer in the men. Neither was vitamin E, or selenium and vitamin E together.

The Safety Monitoring Committee was also concerned that more new cases of diabetes occurred in men taking selenium alone, compared to the men taking the placebo, although this difference was not quite statistically significant (p=.08). (Vitamin E

⁹ BJU International 2003; 91: 608-612.

¹⁰ Ann Intern Med 2007; 147: 217-223.

¹¹ Ann Intern Med. 2007 Aug 21;147(4):114.

appeared to spur prostate cancer, although that, too, did not quite reach statistical significance (p=.09)).

Despite the public announcement last October of the failure of the SELECT trial to find any effect of selenium on prostate cancer risk, and despite the increased risk of diabetes seen in the NPC study and the possible increased risk of diabetes in the SELECT trial, Bayer continues to advertise the selenium in its men's multis as a way to prevent prostate cancer.

In January 2009, the details of the SELECT trial were published in the Journal of the American Medical Association (JAMA) for all to read. The authors' conclusion: "Selenium or vitamin E, alone or in combination at the doses and formulations used, did not prevent prostate cancer in this population of relatively healthy men."¹²

In an editorial accompanying the study's publication, Peter Gann of the University of Illinois at Chicago advised, based on the SELECT trial results, that: "...physicians should not recommend selenium or vitamin E—or any other antioxidant supplements—to their patients for preventing prostate cancer."¹³

Despite the publication in JAMA of the SELECT trial's failure to find any effect of selenium on prostate cancer risk, Bayer continues to promote in television and radio advertising and on its website the selenium in its men's multis as a way to prevent prostate "issues" and prostate cancer.

New Study of Selenium Fails to Prevent Prostate Cancer

In April 2009, Canadian researchers released the results of a new three-year trial of selenium, vitamin E, and soy in men with high-grade prostatic intraepithelial neoplasia (HGPIN). The combination therapy did not halt the progression of the lesions to prostate cancer.

"The results of this study support the findings of the SELECT trial which also demonstrated no benefit using Vitamin E and selenium," said Christopher Amling, MD, a spokesman for the American Urological Association, at whose annual meeting the results of this trial were presented. "These studies highlight the importance of conducting randomized trials of these agents since many of these supplements are promoted falsely to the general public as having beneficial effects on cancer prevention and progression."¹⁴

Violation of Previous Bayer Consent Decree with the FTC

¹² JAMA. 2009 Jan 7;301(1):39-51.

¹³ JAMA. 2009 Jan 7;301(1):102-3.

¹⁴ http://www.aunet.org/content/press/press_releases/article.cfm?articleNo=115

Bayer's false claims about the ability of its selenium-containing One A Day multivitamins to lower the risk of prostate cancer violate the terms of the consent decree the company signed with the Federal Trade Commission in January, 2007.¹⁵

In that case, the FTC charged Bayer with making unsubstantiated claims about another One A Day multivitamin called WeightSmart, and the company paid a \$3.2 million civil penalty. The FTC alleged that these unsubstantiated claims violated a 1991 Commission order against Bayer's predecessor, Miles Inc., that require all claims about the benefits of One A Day brand products to be substantiated by competent and reliable scientific evidence.

In the 2007 agreement, Bayer was once again prohibited from violating the earlier FTC order and in the future from "making unsubstantiated representations regarding the benefits, performance, efficacy, safety, or side effects of any dietary supplement, multivitamin, or weight-control product."

Bayer has clearly violated this agreement again.

Bayer is currently running corrective advertising in the U.S. for its Yaz brand of contraceptive, as part of a settlement with the Food and Drug Administration (FDA) and the attorneys general of 27 states, who accused Bayer of overstating the benefits and downplaying the risks of the drug. Bayer has agreed to spend at least \$20 million on corrective ads in 2009 and to submit for screening by FDA all of its proposed Yaz ads for the next six years.¹⁶

Action Requested

We urge the Federal Trade Commission to take swift and strong action to get these deceptive Bayer ads off television, radio, and the Internet and out of newspapers and magazines or wherever else they may be displayed.

Since these ads have run so often for so long, deeply reinforcing the false notion that selenium is protective against prostate cancer, and because selenium supplementation may actually be harmful by increasing the risk of diabetes, the FTC should require Bayer to run corrective advertising.

And we urge that strong monetary sanctions be imposed on Bayer for repeatedly violating its agreements with the FTC, both to encourage better behavior by that company and as an example to other companies.

¹⁵ <http://www.ftc.gov/os/caselist/bayercorp/070104consentdecree.pdf>

¹⁶ <http://www.nytimes.com/2009/02/11/business/11pill.html>

For the foregoing reasons, we request that the Commission:

- (1) Bring an action pursuant to Section 13 of the FTCA, 15 U.S.C. § 53, to enjoin further distribution of any advertisements by Bayer regarding the impact of selenium supplement consumption and prostate health pending issuance of a complaint under Section 5 of the FTCA, 15 U.S.C. § 45;
- (2) Initiate action under Section 5 of the Act, 15 U.S.C. § 45, to permanently prohibit dissemination of the advertisements;
- (3) Require the payment of a monetary penalty; and
- (4) Require corrective advertising.

Sincerely,



David Schardt, MS
Senior Nutritionist



Katherine Campbell
Staff Attorney

Michael F. Jacobson, Ph.D.
Executive Director

Directions: Adults, One (1) daily, with food.

Supplement Facts

Serving Size: One tablet

	Amount Per Serving	% Daily Value		Amount Per Serving	% Daily Value		Amount Per Serving	% Daily Value
Vitamin A (14% as beta-carotene)	3500 IU	70%	Vitamin B ₆	3 mg	150%	Selenium	105 mcg	150%
Vitamin C	90 mg	150%	Folic Acid	400 mcg	100%	Copper	2 mg	100%
Vitamin D	400 IU	100%	Vitamin B ₁₂	18 mcg	300%	Manganese	2 mg	100%
Vitamin E	45 IU	150%	Biotin	30 mcg	10%	Chromium	120 mcg	100%
Vitamin K	20 mcg	25%	Pantothenic Acid	5 mg	50%	Potassium	100 mg	3%
Thiamin (B ₁)	1.2 mg	80%	Calcium (elemental)	210 mg	21%	Lycopene	600 mcg	*
Riboflavin (B ₂)	1.7 mg	100%	Iron	0 mg	0%	*Daily Value not established.		
Niacin	16 mg	80%	Magnesium	120 mg	30%			
			Zinc	15 mg	100%			

INGREDIENTS: Calcium Carbonate, Magnesium Oxide, Potassium Chloride, Cellulose, Ascorbic Acid, dl-Alpha-Tocopheryl Acetate, Corn Starch, Croscarmellose Sodium, Acacia, D-Calcium Phosphate, Zinc Oxide, Nicotinamide, Gelatin, Stearic Acid, Silicon Dioxide, Dextrin, Magnesium Stearate, D-Calcium Pantothenate, Manganese Sulfate, Pyridoxine Hydrochloride, Hydroxypropyl Cellulose, Cupric Oxide, Calcium Silicate, Pepsin, Glucose, Riboflavin, Sucrose, Vitamin A Acetate, Thiamine Mononitrate, Dextrose, Soy Lactin, Chromium Chloride, Lycopene, Folic Acid, Sorbitol Carboxymethylcellulose, Beta-Carotene, Sodium Selenate, Sodium Citrate, Inositol Hexanic Phosphate, Sodium Ascorbate, Tocopherols, Biotin, Phytonadione, Cyanocobalamin, Ergocalciferol, Ascorbyl Palmitate. Contains: Fish (cod, pollock, haddock, hake, cusk, rockfish) and Soy.

THE COMPLETE MULTIVITAMIN PLUS MORE[†] FOR MEN

Did you know that prostate cancer is the most frequently diagnosed cancer in men and that emerging research suggests Selenium may reduce the risk of prostate cancer? One A Day[®] Men's Health Formula is a complete multivitamin plus key nutrients including Selenium to support a healthy prostate. Selenium may reduce the risk of certain cancers. Some scientific evidence suggests that consumption of Selenium may reduce the risk of certain forms of cancer. However, FDA has determined that this evidence is limited and not conclusive.*

[†]Compared to One A Day[®] Essential, and with nearly twice the Selenium in Centrum[®] for prostate health.

*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Directions: Adults: Take one tablet daily, with food.

Supplement Facts

Serving Size: One tablet

Amount Per Serving	% Daily Value	Amount Per Serving	% Daily Value	Amount Per Serving	% Daily Value
Total Carbohydrate	< 1g < 1%*	Vitamin B6	6 mg 300%	Selenium	105 mcg 150%
Vitamin A (20% as beta-carotene)	2500 IU 50%	Folic Acid	400 mcg 100%	Copper	2 mg 100%
Vitamin C	120 mg 200%	Vitamin B12	25 mcg 417%	Manganese	4 mg 200%
Vitamin D	400 IU 100%	Biotin	30 mcg 10%	Chromium	180 mcg 150%
Vitamin E	33 IU 110%	Pantothenic Acid	15 mg 150%	Molybdenum	90 mcg 120%
Vitamin K	20 mcg 25%	Calcium (elemental)	120 mg 12%	Potassium	40 mg 1%
Thiamin (B1)	4.5 mg 300%	Iron	0 mg 0%	Ginkgo Biloba Extract (leaf)	120 mg **
Riboflavin (B2)	3.4 mg 200%	Iodine	150 mcg 100%	Lycopene	600 mcg **
Niacin	20 mg 100%	Magnesium	100 mg 25%		
		Zinc	22.5 mg 150%		

*Percent Daily Values are based on a 2,000 calorie diet.
**Daily Value not established.

INGREDIENTS: Calcium Carbonate, Cellulose, Magnesium Oxide, Ascorbic Acid, Ginkgo Biloba Extract (leaf), Potassium Chloride, Corn Starch, Octadecylm Phosphate, dl-Alpha-Tocopheryl Acetate, Croscarmellosem Sodium, Zinc Oxide, Polyvinyl Alcohol, Niacinamide, D-Calcium Pantothenate, L-Ascorbyl Polysorbate, Silicon Dioxide, Titanium Dioxide, Polyethylene Glycol, Manganese Sulfate, Gelatin, Talc, Malto-Dextrin, Acacia, Polydextrose, Hydroxypropyl Methylcellulose, Magnesium Stearate, Cupric Sulfate, Triaminic Monohydrate, Hypromellose, Polyethylene Glycol, Sodium Stearoyl Fatty Acid Salt, Chromium Chloride, Vitamin A Acetate, Lycopene, Folic Acid, Beta-Carotene, Sodium Selenate, Sodium Molybdate, Potassium Iodide, Tricalcium Phosphate, Sodium Ascorbate, Tocopherols, F.F.C. Base #1 Lake, Biotin, Cyanocobalamin, Pyridoxine, Cholecalciferol, Ascorbyl Palmitate.

Ask a doctor before use if you are taking a drug for anticoagulation (thinning the blood), including daily aspirin. Before surgery, ask your doctor about continued use.

A MULTIVITAMIN SPECIALLY FORMULATED FOR MEN OVER 50
*As a man over 50, you don't have to settle for an all-purpose multivitamin. You can take one that is specially formulated for both your age and gender. One A Day Men's 50+ Advantage contains Lycopene and nearly twice the Selenium in Centrum® Silver® to support prostate health and it provides key nutrients to support heart health, eye health, and healthy blood pressure.†† Plus, it contains Ginkgo to promote memory and concentration.**

†† To help maintain blood pressure levels already within the normal range

*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.



June 18, 2009

VIA REGULAR MAIL AND FAX TO 973-254-4853

Gary S. Balkema, President
Consumer Care Division
Bayer HealthCare LLC
36 Columbia Rd
Morristown, NJ 07962-1910

Re: Bayer's false and deceptive marketing for its Men's Multis for prevention of cancer

Dear Mr. Balkema:

The Center for Science in the Public Interest ("CSPI") intends to file a lawsuit against Bayer HealthCare LLC ("Bayer") for fraudulent and deceptive practices in the marketing and sale of Bayer's One A Day Men's 50+ Advantage multivitamin and Bayer's One A Day Men's Health Formula multivitamin (jointly, "Men's Multis").

This letter describes Bayer's illegal practices and offers settlement to avoid the necessity of a lawsuit.

If litigation is necessary, CSPI plans to seek an injunction prohibiting Bayer from representing (either expressly or implicitly) that any of its products can be used in the diagnosis, cure, mitigation, treatment, or prevention of disease. CSPI also may seek corrective advertising, restitution, damages, disgorgement, and attorneys' fees.

Facts Giving Rise to Bayer's Liability

The details of Bayer's wrongdoing are set out in a complaint CSPI is filing today with the Federal Trade Commission, a copy of which is attached and incorporated herein by this reference. In summary, these are the facts giving rise to Bayer's liability:

Bayer promotes the extra selenium in its Men's Multis for the mitigation, prevention, treatment, or cure of prostate cancer in several ways: on package labels, on its website, and in television and radio advertisements. Bayer has run at least 11 different television ads and at least 9 different radio ads since 2008 linking its men's multivitamins to the prevention of prostate cancer.

For example, the back of the package for One A Day Men's Health Formula bears this claim:

Did you know that prostate cancer is the most frequently diagnosed cancer in men and that emerging research suggests Selenium may reduce the risk of prostate cancer?

Similarly, one of the radio ads claims:

Prostate cancer. It's an important subject. Did you know that there are more new cases of prostate cancer each year than any other cancer? And here's something else you should know. Now, there's something that you can do that may help reduce your risk. Along with your regular doctor checkups, switch to One A Day men's. A complete multivitamin plus selenium, which emerging research suggests may reduce the risk of prostate cancer. One A Day Men's. Because staying healthy is serious business.

Bayer's website expands on these claims:

Did you know that 1 in 6 men will face prostate issues? Prostate cancer is the most frequently diagnosed non-skin cancer in men, and emerging research suggests Selenium may reduce the risk of prostate cancer.

The attached FTC complaint discusses the research in detail, but, in summary, the research does not substantiate Bayer's cancer claims—and in fact shows that the amount of selenium in the Men's Multis may be harmful.

The Nutritional Prevention of Cancer (NPC) trial, upon which Bayer presumably relies, shows that the benefit of selenium supplementation for the prevention of prostate cancer was limited to a very small subgroup of men with the lowest levels of blood selenium and low baseline PSA scores.

More importantly, analysis of the NPC data found nearly a three-fold increased risk of diabetes in the men who were assigned to take selenium and who had the highest levels of blood selenium at the start of the trial.

In making its claims, Bayer ignores the findings of the federally funded Selenium and Vitamin E Cancer Prevention Trial (SELECT), the most important and compelling study. It did not find any evidence that selenium reduces the risk of prostate cancer in average, healthy men.

The SELECT trial was designed to last up to 12 years. However, in October 2008, it was abruptly terminated after the study's independent Data and Safety Monitoring Committee reviewed the SELECT data up to that point and concluded that selenium and vitamin E, alone or together, did not prevent prostate cancer in men.

The Data and Safety Monitoring Committee was also concerned that more new cases of diabetes may have occurred in men taking selenium alone, compared to the men taking the placebo.

In January 2009, the details of the SELECT trial were published in the Journal of the American Medical Association for all to read. The authors' conclusion: "Selenium or vitamin E, alone or in combination at the doses and formulations used, did not prevent prostate cancer in this population of relatively healthy men."

In fact, the American College of Physicians recommends against use of selenium supplements:

Selenium supplements appear to increase the risk for diabetes. Although the findings need to be confirmed, long-term selenium supplementation should not be viewed as harmless and a possibly healthy way to prevent illness.

Despite the public announcement of the failure of the SELECT trial to find any effect of selenium on prostate cancer risk, despite the possible increased risk of diabetes, and despite the recommendations of the American College of Physicians, Bayer continues to advertise the selenium in its Men's Multis as a way to prevent prostate cancer.

If Bayer has additional scientific substantiation for its prostate cancer claims for Men's Multis, please provide it to me as soon as possible. In the absence of being provided with such additional substantiation, CSPI will presume that none exists.

Bayer's Multiple Violations of State Consumer Protection Laws

Bayer's claims (1) are illegal claims of disease prevention, (2) do not have prior substantiation, (3) fail to warn of the possible increased risk of diabetes, and (4) are generally false, misleading, and deceptive.

Therefore, the labeling and marketing of these Men's Multis are unfair and deceptive under state consumer protections laws, such as Massachusetts G.L. c. 93A, Texas Business & Professions Code § 17.41 *et seq.*, District of Columbia Code § 28-3905 *et seq.*, New Jersey Statutes Ann. 56:8-1 *et seq.*, California Business & Professions Code Sections 17200 and 17500, and California Civil Code §§ 1770(a)(5) & 1770(a)(14) (jointly, "UDAP" laws).

For the same reasons, these Men's Multis are both "adulterated" and "misbranded" in violation of state food and drug laws, such as the California Food, Drug, and Cosmetic Act, California Health and Safety Code § 110660.

As the manufacturer and distributor of these Men's Multis, Bayer is responsible for the injuries caused by its actions. Consumer injury occurs each time a consumer sees marketing for or purchases one of these products. Each occurrence is a separate injury. *E.g., Aspinnall v. Philip Morris Companies, Inc.*, 442 Mass. 381, 813 N.E.2d 476 (Mass. 2004).

Settlement Demand

In light of the foregoing, CSPI demands the following to settle this matter at this time before filing suit:

- Entry of a permanent injunction that prohibits Bayer from representing (either expressly or implicitly) that any of its products can be used in the diagnosis, cure, mitigation, treatment, or prevention of disease.
- Entry of a permanent injunction that prohibits Bayer from any representation with respect to any disease for its Men's Multi's.
- Entry of a permanent injunction that mandates a series of corrective advertisements to correct Bayer's prior consumer deception with respect to the cancer-preventative benefits of its Men's Multis.
- Disgorgement of Bayer's profits from the sale of its Men's Multis since 2002, when it began making prostate claims.

This offer of settlement will remain open for 30 days from the date of this letter, pursuant to Cal. Civ. Code Sec. 1782 and other state statutory notice requirements, after which it shall be automatically withdrawn and become null and void.

Please have your own counsel contact me if Bayer is willing to discuss settlement or needs additional information about this lawsuit.

Yours truly,



Stephen Gardner
Litigation Director

cc: Michael F. Jacobson, Ph.D., Executive Director
Katherine Campbell, Staff Attorney

Directions: Adults: One tablet daily, with food.

Supplement Facts

Serving Size: One tablet

	Amount Per Serving	% Daily Value		Amount Per Serving	% Daily Value		Amount Per Serving	% Daily Value
Vitamin A (14% as beta-carotene)	3500 IU	70%	Vitamin B ₆	3 mg	150%	Selenium	105 mcg	150%
Vitamin C	90 mg	150%	Folic Acid	400 mcg	100%	Copper	2 mg	100%
Vitamin D	400 IU	100%	Vitamin B ₁₂	18 mcg	300%	Manganese	2 mg	100%
Vitamin E	45 IU	150%	Biotin	30 mcg	10%	Chromium	120 mcg	100%
Vitamin K	20 mcg	25%	Pantothenic Acid	5 mg	50%	Potassium	100 mg	3%
Thiamin (B ₁)	1.2 mg	80%	Calcium (elemental)	210 mg	21%	Lycopene	600 mcg	*
Riboflavin (B ₂)	1.7 mg	100%	Iron	0 mg	0%			
Niacin	16 mg	80%	Magnesium	120 mg	30%			
			Zinc	15 mg	100%			

* Daily Value not established.

INGREDIENTS: Calcium Carbonate, Magnesium Oxide, Potassium Chloride, Cellulose, Ascorbic Acid, dl-Alpha-Tocopheryl Acetate, Corn Starch, Croscarmellose Sodium, Acacia, Dicalcium Phosphate, Zinc Oxide, Niacinamide, Gelatin, Stearic Acid, Silicon Dioxide, Dextrin, Magnesium Stearate, D-Calcium Pantothenate, Manganese Sulfate, Pyridoxine Hydrochloride, Hypromellose, Cupric Oxide, Calcium Silicate, Resin, Glucose, Riboflavin, Sucrose, Vitamin A Acetate, Thiamine Mononitrate, Dextrose, Soy Lecithin, Chromium Chloride, Lycopene, Folic Acid, Sodium Carboxymethylcellulose, Beta-Carotene, Sodium Selenate, Sodium Citrate, Tricalcium Phosphate, Sodium Ascorbate, Tocopherols, Biotin, Phytonadione, Cyanocobalamin, Ergocalciferol, Ascorbyl Palmitate.
 Contains: Fish (cod, pollock, haddock, hake, cusk, redfish) and Soy.

THE COMPLETE MULTIVITAMIN PLUS MORE[†] FOR MEN

Did you know that prostate cancer is the most frequently diagnosed cancer in men and that emerging research suggests Selenium may reduce the risk of prostate cancer? One A Day[®] Men's Health Formula is a complete multivitamin plus key nutrients including Selenium to support a healthy prostate.* Selenium may reduce the risk of certain cancers. Some scientific evidence suggests that consumption of Selenium may reduce the risk of certain forms of cancer. However, FDA has determined that this evidence is limited and not conclusive.

[†] Compared to One A Day[®] Essential, and with nearly twice the Selenium in Centrum[®] for prostate health

* This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

ONE A DAY

Men's Health Formula

KEEP OUT OF REACH OF CHILDREN
 CHILD RESISTANT CAP

Do not use this product if safety seal bearing "SEALED for YOUR PROTECTION" under cap is torn or missing.

EXPIRATION DATE:

Key Ingredients for Men: *

HEARTY HEART: Lycopene, Selenium, Vitamin E, Zinc

HEALTHY PROSTATE: Vitamins B6, B12, C, E, Folic Acid

HEALTHY EYES: Vitamins A, C, E, Zinc

ENERGY BLOOD PRESSURE: Vitamin B6, Biotin, Magnesium, Xanthin, Pantothenic Acid, Riboflavin, Thiamin; Calcium, Magnesium, Vitamin C

^{††} To help maintain blood pressure levels already within the normal range.

* This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

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 Centrum is a trademark of Wyeth Holdings Corporation.
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Made in U.S.A.
 Distributed by:
 Bayer HealthCare
 Consumer Care
 P.O. Box 1910
 Morrisville, NJ 07962-1910 USA

Questions or comments?
 Please call 1-800-800-4733 (Mon-Fri 9-5 EST)
 Visit our website at www.oneaday.com



ONE A DAY *Men's Health Formula*

Complete Multivitamin Plus More[†] for Men to Support:^{*}

- Prostate Health
- Heart Health
- Healthy Blood Pressure^{††}

OFFICIAL SPONSOR



† Compared to One A Day Basic, and with nearly twice the Selenium in Cetrarum® for prostate health.
^{*} This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

ONE A DAY *Men's Health Formula*

Complete Multivitamin Plus More[†] for Men to Support:^{*}

- Prostate Health with Lycopene, more[†] Selenium, Vitamin E and Zinc
- Heart Health with Vitamins B6, B12, C, E and Folic Acid
- Healthy Blood Pressure^{††} with Calcium, Magnesium and Vitamin C

Does Not Contain Iron - Research suggests excess iron may increase a man's risk of heart disease

^{††} To help maintain blood pressure levels already within the normal range

SUPPORTS PROSTATE HEALTH^{*}

ONE A DAY
 MULTIVITAMIN/MULTIMINERAL SUPPLEMENT

Men's Health Formula

60 TABLETS

HOME PRODUCTS FAQs HEALTH & WELLNESS KIDS MULTIVITAMINS

STRIKEOUT PROSTATE
CANCER CHALLENGE

ONE A DAY Men's Presents MAJOR LEAGUE BASEBALL® STRIKEOUT PROSTATE CANCER CHALLENGE



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ONE A DAY® and MLB® are teaming up to support the Prostate Cancer Foundation.

- CONTACT US
- WHERE TO BUY

BAYER LINKS
- BAYER GLOBAL
- BAYER US
- BAYER CONSUMER CARE

● 1 in 6 men face prostate cancer and that is why One A Day and MLB® will donate \$10 for every strikeout this season to support prostate health awareness and research.

● One A Day Men's and Men's 50+ Advantage are complete Multivitamins specially formulated for men to support Prostate Health.

HOME | PRODUCTS | WHAT'S YOUR ONE A DAY? | FAQs | HEALTH & WELLNESS | KIDS MULTIVITAMINS

Attachment D

ONE A DAY PRODUCTS

- WOMEN'S
- WOMEN'S₂O
- MEN'S HEALTH FORMULA
- WOMEN'S 50+ ADVANTAGE
- MEN'S 50+ ADVANTAGE
- WOMEN'S PRENATAL
- WOMEN'S ACTIVE MIND & BODY
- WEIGHTSMART ADVANCED
- CHOLESTEROL PLUS
- ENERGY
- ENERGY ADVANTAGE₂O
- MAXIMUM
- ESSENTIAL
- TEEN ADVANTAGE
- VITACRAVES GUMMIES

- CONTACT US
- WHERE TO BUY

BAYER LINKS

- BAYER GLOBAL
- BAYER US
- BAYER CONSUMER CARE



One A Day Men's
A Complete Multivitamin
Plus More[†] for Men.



Prostate cancer is the most frequently diagnosed non-skin cancer in men, and emerging research suggests Selenium may reduce the risk of prostate cancer^{**}. One A Day[®] Men's Health Formula is a complete multivitamin plus key nutrients to support a healthy heart, and Selenium to support a healthy prostate.*

Complete Multivitamin Plus More[†] for Men to Support:[†]
Prostate Health with Lycopene, more[†] Selenium, Vitamin E and Zinc
Heart Health with Vitamins B6, B12, C, E and Folic Acid
Healthy Blood Pressure^{††} with Calcium, Magnesium and Vitamin C

Does Not Contain Iron – Research suggests excess iron may increase a man's risk of heart disease

[†]Compared to One A Day[®] Essential, and nearly twice the Selenium in Centrum[®] for prostate health

^{††}To help maintain blood pressure levels already within the normal range

^{**}See packaging for information about Selenium and certain cancers

*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

[Directions](#) | [Ingredients](#) | [Warnings](#)

DIRECTIONS:
Adults: One tablet daily, with food.
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SUPPLEMENT FACTS		
Serving Size: One tablet		
	Amount Per Serving	% Daily Value
Vitamin A (14% as beta-carotene)	3500 IU	70%
Vitamin C	90 mg	150%
Vitamin D	400 IU	100%
Vitamin E	45 IU	150%
Vitamin K	20 mcg	25%
Thiamin (B1)	1.2 mg	80%
Riboflavin (B2)	1.7 mg	100%
Niacin	16 mg	80%
Vitamin B6	3 mg	150%
Folic Acid	400 mcg	100%
Vitamin B12	18 mcg	300%
Biotin	30 mcg	10%
Pantothenic Acid	5 mg	50%
Calcium (elemental)	210 mg	21%
Iron	0 mg	0%
Magnesium	120 mg	30%
Zinc	15 mg	100%
Selenium	105 mcg	150%
Copper	2 mg	100%
Manganese	2 mg	100%
Chromium	120 mcg	100%
Potassium	100 mg	3%

Attachment E

Lycopene	600 mcg	*
*Daily Value not established.		

INGREDIENTS:

Calcium Carbonate, Magnesium Oxide, Potassium Chloride, Cellulose, Ascorbic Acid, dl-Alpha-Tocopheryl Acetate, Corn Starch, Croscarmellose Sodium, Acacia, Dicalcium Phosphate, Zinc Oxide, Niacinamide, Gelatin, Stearic Acid, Silicon Dioxide, Dextrin, Magnesium Stearate, D-Calcium Pantothenate, Manganese Sulfate, Pyridoxine Hydrochloride, Hypromellose, Cupric Oxide, Calcium Silicate, Resin, Glucose, Riboflavin, Sucrose, Vitamin A Acetate, Thiamine Mononitrate, Dextrose, Soy Lecithin, Chromium Chloride, Lycopene, Folic Acid, Sodium Carboxymethylcellulose, Beta-Carotene, Sodium Selenate, Sodium Citrate, Tricalcium Phosphate, Sodium Ascorbate, Tocopherols, Biotin, Phytonadione, Cyanocobalamin, Ergocalciferol, Ascorbyl Palmilate.

Contains: Fish (cod, pollock, haddock, hake, cusk, redfish) and Soy.

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KEEP OUT OF REACH OF CHILDREN

CHILD RESISTANT CAP

Do not use this product if safety seal bearing "SEALED for YOUR PROTECTION" under cap is torn or missing.

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Attachment E

HOME PRODUCTS FAQs HEALTH & WELLNESS KIDS MULTIVITAMINS

ONE A DAY PRODUCTS

- WOMEN'S
- WOMEN'S₂O
- MEN'S HEALTH FORMULA
- WOMEN'S 50+ ADVANTAGE
- MEN'S 50+ ADVANTAGE
- WOMEN'S PRENATAL
- WOMEN'S ACTIVE MIND & BODY
- WEIGHTSMART ADVANCED
- CHOLESTEROL PLUS
- ENERGY
- ENERGY ADVANTAGE₂O
- MAXIMUM
- ESSENTIAL
- TEEN ADVANTAGE
- VITACRAVES GUMMIES

- CONTACT US
- WHERE TO BUY

- BAYER LINKS
- BAYER GLOBAL
 - BAYER US
 - BAYER CONSUMER CARE



One A Day® Men's Health Formula is a complete multivitamin plus key nutrients to support a healthy heart, and Selenium to support a healthy prostate.*

Complete Multivitamin Plus More¹ for Men to Support:^{*}

- Prostate Health with Lycopene, more¹ Selenium, Vitamin E and Zinc
- Heart Health with Vitamins B6, B12, C, E and Folic Acid
- Healthy Blood Pressure¹¹ with Calcium, Magnesium and Vitamin C

Does Not Contain Iron – Research suggests excess iron may increase a man's risk of heart disease

¹Compared to One A Day® Essential, and nearly twice the Selenium in Centrum® for prostate health

¹¹To help maintain blood pressure levels already within the normal range

*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

[Directions](#) | [Ingredients](#) | [Warnings](#)

DIRECTIONS:

Adults: One tablet daily, with food.

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SUPPLEMENT FACTS		
Serving Size: One tablet		
	Amount Per Serving	% Daily Value
Vitamin A (14% as beta-carotene)	3500 IU	70%
Vitamin C	90 mg	150%
Vitamin D	400 IU	100%
Vitamin E	45 IU	150%
Vitamin K	20 mcg	25%
Thiamin (B1)	1.2 mg	80%
Riboflavin (B2)	1.7 mg	100%
Niacin	16 mg	80%
Vitamin B6	3 mg	150%
Folic Acid	400 mcg	100%
Vitamin B12	18 mcg	300%
Biotin	30 mcg	10%
Pantothenic Acid	5 mg	50%
Calcium (elemental)	210 mg	21%
Iron	0 mg	0%
Magnesium	120 mg	30%
Zinc	15 mg	100%
Selenium	105 mcg	150%
Copper	2 mg	100%
Manganese	2 mg	100%
Chromium	120 mcg	100%
Potassium	100 mg	3%
Lycopene	600 mcg	*

*Daily Value not established.

Attachment E

INGREDIENTS:

Calcium Carbonate, Magnesium Oxide, Potassium Chloride, Cellulose, Ascorbic Acid, dl-Alpha-Tocopheryl Acetate, Corn Starch, Croscarmellose Sodium, Acacia, Dicalcium Phosphate, Zinc Oxide, Niacinamide, Gelatin, Stearic Acid, Silicon Dioxide, Dextrin, Magnesium Stearate, D-Calcium Pantothenate, Manganese Sulfate, Pyridoxine Hydrochloride, Hypromellose, Cupric Oxide, Calcium Silicate, Resin, Glucose, Riboflavin, Sucrose, Vitamin A Acetate, Thiamine Mononitrate, Dextrose, Soy Lecithin, Chromium Chloride, Lycopene, Folic Acid, Sodium Carboxymethylcellulose, Beta-Carotene, Sodium Selenate, Sodium Citrate, Tricalcium Phosphate, Sodium Ascorbate, Tocopherols, Biotin, Phytonadione, Cyanocobalamin, Ergocalciferol, Ascorbyl Palmitate.

Contains: Fish (cod, pollock, haddock, hake, cusk, redfish) and Soy.

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KEEP OUT OF REACH OF CHILDREN

CHILD RESISTANT CAP

Do not use this product if safety seal bearing "**SEALED for YOUR PROTECTION**" under cap is torn or missing.

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Attachment E

HOME PRODUCTS FAQs HEALTH & WELLNESS KIDS MULTIVITAMINS

ONE A DAY PRODUCTS

- WOMEN'S
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- MEN'S HEALTH FORMULA
- WOMEN'S 50+ ADVANTAGE
- MEN'S 50+ ADVANTAGE
- WOMEN'S PRENATAL
- WOMEN'S ACTIVE MIND & BODY
- WEIGHTSMART ADVANCED
- CHOLESTEROL PLUS
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- ENERGY ADVANTAGE 20
- MAXIMUM
- ESSENTIAL
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- CONTACT US
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- BAYER GLOBAL
- BAYER US
- BAYER CONSUMER CARE



One A Day Men's 50+ Advantage
 A Complete Multivitamin Plus More[†] Specially Formulated for Men over 50.



As a man over 50, you can take a multivitamin that is specially formulated for both your age and gender. One A Day[®] Men's 50+ Advantage contains Selenium to support prostate health and it provides key nutrients to support heart health, eye health and healthy blood pressure.^{**} Plus, it contains Ginkgo to promote memory and concentration.*

- Complete Multivitamin Plus More[†] to Support:
- Memory and Concentration with Ginkgo
 - Prostate Health with Lycopene, more[†] Selenium, Vitamin E and Zinc
 - Heart Health with Vitamins B6, B12, C, E and Folic Acid
 - Healthy Blood Pressure^{**} with Calcium, Magnesium and Vitamin C
 - Eye Health with Vitamins E, A, C and Zinc

Does Not Contain Iron – Research suggests excess iron may increase a man's risk of heart disease

[†]Compared to One A Day[®] Essential, and with nearly twice the Selenium in Centrum[®] Silver[®] for prostate health

^{**}To help maintain blood pressure levels already within the normal range

*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

[Directions](#) | [Ingredients](#) | [Warnings](#)

DIRECTIONS:
 Adults: Take one tablet daily, with food.

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SUPPLEMENT FACTS		
Serving Size: One tablet		
	Amount Per Serving	% Daily Value
Total Carbohydrate	< 1 g	< 1%*
Vitamin A (20% as beta-carotene)	2500 IU	50%
Vitamin C	120 mg	200%
Vitamin D	400 IU	100%
Vitamin E	33 IU	110%
Vitamin K	20 mcg	25%
Thiamin (B1)	4.5 mg	300%
Riboflavin (B2)	3.4 mg	200%
Niacin	20 mg	100%
Vitamin B6	6 mg	300%
Folic Acid	400 mcg	100%
Vitamin B12	25 mcg	417%
Biotin	30 mcg	10%
Pantothenic Acid	15 mg	150%
Calcium (elemental)	120 mg	12%
Iron	0 mg	0%
Iodine	150 mcg	100%
Magnesium	100 mg	25%
Zinc	22.5 mg	150%
Selenium	105 mcg	150%
Copper	2 mg	100%

Attachment F

Manganese	4 mg	200%
Chromium	180 mcg	150%
Molybdenum	90 mcg	120%
Potassium	40 mg	1%
Ginkgo Biloba Extract (leaf)	120 mg	**
Lycopene	600 mcg	**
*Percent Daily Values are based on a 2,000 calorie diet.		
**Daily Value not established.		

INGREDIENTS:

Calcium Carbonate, Cellulose, Magnesium Oxide, Ascorbic Acid, Ginkgo Biloba Extract (leaf), Potassium Chloride, Corn Starch, Dicalcium Phosphate, dl-Alpha- Tocopheryl Acetate, Croscarmellose Sodium, Zinc Oxide, Polyvinyl Alcohol, Niacinamide, D-Calcium Pantothenate, Crospovidone, Silicon Dioxide, Titanium Dioxide, Polyethylene Glycol, Manganese Sulfate, Gelatin, Talc, Maltodextrin, Acacia, Pyridoxine Hydrochloride, Magnesium Stearate, Cupric Sulfate, Thiamine Mononitrate, Hypromellose, Riboflavin, Glucose, Sucrose, FD&C Blue #2 Lake, Chromium Chloride, Vitamin A Acetate, Lycopene, Folic Acid, Beta-Carotene, Sodium Selenate, Sodium Molybdate, Potassium Iodide, Tricalcium Phosphate, Sodium Ascorbate, Tocopherols, FD&C Blue #1 Lake, Biotin, Cyanocobalamin, Phytonadione, Cholecalciferol, Ascorbyl Palmitate

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Ask a doctor before use if you are taking a drug for anticoagulation (thinning the blood), including daily aspirin.

Before surgery, ask your doctor about continued use.

KEEP OUT OF REACH OF CHILDREN

Do not use this product if safety seal bearing "SEALED for YOUR PROTECTION" under cap is torn or missing.

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Attachment F

ONE A DAY Men's 50+ Advantage

Complete Multivitamin Plus More¹ to Support:^{*}

- Memory & Concentration
- Prostate Health
- Heart Health
- Healthy Blood Pressure^{††}
- Eye Health

OFFICIAL SPONSOR



¹ Compared to One A Day Essential, and with nearly twice the Selenium in Centrum[®] Silver[®] for prostate health.
^{††} To help maintain blood pressure levels already within the normal range.

^{*} This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

ONE A DAY Men's 50+ Advantage

Complete Multivitamin Plus More¹ to Support:^{*}

- Memory and Concentration with Ginkgo
- Prostate Health with Lycopene, more¹ Selenium, Vitamin E and Zinc
- Heart Health with Vitamins B6, B12, C, E and Folic Acid
- Healthy Blood Pressure^{††} with Calcium, Magnesium and Vitamin C
- Eye Health with Vitamins E, A, C and Zinc

Does Not Contain Iron

**BONUS
20%
MORE!**

ONE A DAY

With Memory Support^{*}

MULTIVITAMIN/MULTIMINERAL SUPPLEMENT

Men's 50+ Advantage

60
TABLETS

Key Ingredients for Men Over 50 to Support:



†† To help maintain blood pressure levels already within the normal range.

*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Directions: Adults: Take one tablet daily, with food.

Supplement Facts

Serving Size: One tablet

Amount Per Serving	% Daily Value	Amount Per Serving	% Daily Value	Amount Per Serving	% Daily Value
Total Carbohydrate	< 1 g < 1%*	Vitamin B6	6 mg 300%	Selenium	105 mcg 150%
Vitamin A	2500 IU 50%	Folic Acid	400 mcg 100%	Copper	2 mg 100%
(20% as beta-carotene)		Vitamin B12	25 mcg 417%	Manganese	4 mg 200%
Vitamin C	120 mg 200%	Biotin	30 mcg 10%	Chromium	180 mcg 150%
Vitamin D	400 IU 100%	Pantothenic Acid	15 mg 150%	Molybdenum	90 mcg 120%
Vitamin E	33 IU 110%	Calcium (elemental)	120 mg 12%	Potassium	40 mg 1%
Vitamin K	20 mcg 25%	Iron	0 mg 0%	Ginkgo Biloba Extract (leaf)	120 mg **
Thiamin (B1)	4.5 mg 300%	Iodine	150 mcg 100%	Lycopene	600 mcg **
Riboflavin (B2)	3.4 mg 200%	Magnesium	100 mg 25%		
Niacin	20 mg 100%	Zinc	22.5 mg 150%		

*Percent Daily Values are based on a 2,000 calorie diet.
**Daily Value not established.

INGREDIENTS: Calcium Carbonate, Cellulose, Magnesium Oxide, Ascorbic Acid, Ginkgo Biloba Extract (leaf), Potassium Chloride, Corn Starch, Dicalcium Phosphate, dl-Alpha-Tocopheryl Acetate, Croscarmellose Sodium, Zinc Oxide, Polyvinyl Alcohol, Niacinamide, D-Calcium Pantothenate, Crospovidone, Silicon Dioxide, Titanium Dioxide, Polyethylene Glycol, Manganese Sulfate, Gelatin, Talc, Maltodextrin, Acacia, Pyridoxine Hydrochloride, Magnesium Stearate, Cupric Sulfate, Thiamine Mononitrate, Hypromellose, Riboflavin, Glucose, Sucrose, FD&C Blue #2 Lake, Chromium Chloride, Vitamin A Acetate, Lycopene, Folic Acid, Beta-Carotene, Sodium Selenate, Sodium Molybdate, Potassium Iodide, Tricalcium Phosphate, Sodium Ascorbate, Tocopherols, FD&C Blue #1 Lake, Biotin, Cyanocobalamin, Phytonadione, Cholecalciferol, Ascorbyl Palmitate.

Ask a doctor before use if you are taking a drug for anticoagulation (thinning the blood), including daily aspirin. Before surgery, ask your doctor about continued use.

A MULTIVITAMIN SPECIALLY FORMULATED FOR MEN OVER 50
As a man over 50, you don't have to settle for an all-purpose multivitamin. You can take one that is specially formulated for both your age and gender. One A Day Men's 50+ Advantage contains Lycopene and nearly twice the Selenium in Centrum® Silver® to support prostate health and it provides key nutrients to support heart health, eye health, and healthy blood pressure.†† Plus, it contains Ginkgo to promote memory and concentration.*

†† To help maintain blood pressure levels already within the normal range.

*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

ONE A DAY®

Men's 50+ Advantage

KEEP OUT OF REACH OF CHILDREN
Do not use this product if safety seal bearing "SEALED for YOUR PROTECTION" under cap is torn or missing.

EXPIRATION DATE:

Questions or comments?
Please call 1-800-800-4793 (Mon-Fri 9-5 EST).
Visit our website at www.oneaday.com

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June 18, 2009

Ms. Mary K. Engle
Associate Director
Advertising Practices
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

Dear Ms. Engle,

We are writing to express our support for the Center for Science in the Public Interest's complaint that Bayer Healthcare is making misleading claims in its ads and on its Web site about the role of selenium in preventing prostate cancer.

The seven-year Selenium and Vitamin E Cancer Prevention Trial (SELECT) produced strong evidence last October that selenium does not prevent prostate cancer in a generally healthy, heterogeneous population of men in the United States and Canada. This Federally-financed study was the largest individually randomized cancer prevention trial ever conducted, and, given its high rates of adherence and its statistical power, it is unlikely to have missed detecting a benefit of even a very modest size.

Bayer Healthcare is doing a disservice to men by misleading them about a protective role for selenium in prostate cancer. We ask that you take whatever steps are necessary to halt these ads as soon as possible.

Sincerely,

Peter H. Gann, MD, ScD
Director of the Division of Pathology Research
University of Illinois at Chicago

Michael J. Thun, MD, MS
Vice President Emeritus
Epidemiology and Surveillance Research
American Cancer Society

Edward Giovannucci, MD, ScD
Professor of Nutrition and Epidemiology
Harvard School of Public Health

Tim Byers, MD, MPH
Program Leader for Clinical Cancer Prevention and Control

Attachment G