January 18, 2012

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Risk Assessment on Norovirus in Bivalve Molluscan Shellfish [Docket No. FDA-2011-N-0731]

The Center for Science in the Public Interest (“CSPI”)1, in response to the request in Docket No. FDA-2011-N-0731, submits the attached data on 69 norovirus outbreaks from 1993 to 2009 that are linked to molluscan shellfish.

CSPI maintains a database of foodborne illness outbreaks which to date includes reports between 1990 and 2009. The database covers outbreaks reported by the Centers for Diseases Control and Prevention (“CDC”), supplemented by a small number collected in the earlier years from state health departments’ reports, reports by the CDC’s Foodborne Outbreak Response and Surveillance Unit, and peer-reviewed journal articles. The data is routinely published in Outbreak Alert! and is available on the CSPI website as the searchable Outbreak Alert! Database at http://www.cspinet.org/foodsafety/outbreak/pathogen.php.

We believe several observations about the attached data may be relevant to the risk assessment you are performing. While you have stated that transmission from food service workers is outside the scope of the assessment, the data shows restaurants/food establishments are a vector for 60 percent (42) of the outbreaks. We suggest the assessment should evaluate the potential for contaminated shellfish to be a source of cross contamination in a restaurant setting. Outbreaks caused by shellfish contaminated with norovirus can cause a considerable number of illnesses. The largest outbreak in December 1996 resulted in 493 reported illnesses. Illnesses appear to cluster in the winter months of November to February (43 outbreaks). These are months when the public normally believes oysters are safer to eat. Since thorough cooking kills norovirus, outbreaks are almost always associated with raw shellfish consumption (52 outbreaks).

A risk assessment on norovirus will be helpful to identifying measures that can mitigate or eliminate this source of foodborne disease. However, it begs a question of why the Food and Drug Administration (“FDA”) has not conducted a similar assessment for the more serious shellfish pathogen Vibrio vulnificus. Out of 2,007 illnesses from norovirus outbreaks, only 7

1 The Center for Science in the Public Interest is a nonprofit health advocacy and education organization focused on food safety, nutrition, and alcohol issues. CSPI is supported principally by the 850,000 subscribers to its Nutrition Action HealthLetter and by foundation grants. We accept no government or industry funding.
required hospitalization. For comparison, *V. vulnificus* has a 91 percent hospitalization rate and kills half its victims.

In the period covered by the attached data on norovirus, *V. vulnificus* caused 506 serious illnesses, of which 253 ended in the patient’s death. As with norovirus, we know there are effective interventions that can take place pre-harvest and post-harvest. However, oyster harvesting can proceed in waters infested with *V. vulnificus* and no post-harvest controls other than refrigeration are required. FDA should not ignore the need for a quantitative risk assessment on *V. vulnificus*.

CSPI thanks the agency for taking these comments into consideration as it moves forward with its risk assessment on the sources of foodborne disease.

Sincerely,

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Attachment