

FOODS, INC. & SEAFOOD RESTAURANTS

July 28, 2004

Food and Drug Administration
Division of Dockets Management
5630 Fishers Lane
Rm 1061
Rockville, MD 20852

Re: Docket No. 2002N-0085; Requirements Pertaining to Sampling Services and Private Laboratories Used in Connection With Imported Food

Dear Sir or Madam:

I am writing on behalf of Phillips Foods, Inc., to provide comments on the above-referenced proposed regulations.

Phillips Foods, Inc. ("Phillips") is a Maryland-based seafood manufacturer and wholesaler, with annual sales of approximately \$140 million. Phillips is a leading importer and supplier of pasteurized, canned crabmeat, fish, shrimp as well as other seafood products. We import approximately 600 containers of product per year and have received approximately 30-40 FDA requests for testing and/or sampling this past year

Outlined below are our specific comments:

1. In proposed Section 59.1, the definition of "an FDA enforcement action" is unclear. According to the regulations an enforcement action would "include, but not be limited to, product seizure, refusal of imports, or the issuance of an injunction." Does this apply to detentions without inspection, automatic detentions without examination, or hold designations? We believe that the regulations should clearly state what is included and excluded, since the phrase "include, but not be limited to" could be construed very broadly to include more minor FDA actions.

If the FDA is considering the inclusion of detentions without inspection, automatic detentions without examination or hold designations, we believe that it is overreaching and outside the scope of the intent to deter the importation of unsafe food.

2. FDA has specifically invited comments on whether the regulations should require the use of independent sampling services. Phillips would strongly object to any requirement to use an independent sampling service for the following reasons:

WORLD HEADQUARTERS
1215 E. Fort Avenue, Baltimore, MD 21230, Tel 443/263-1200, 888/234-CRAB, Fax 410/837-8526, www.phillipsfoods.com
New York Baltimore West Palm Beach Dallas Los Angeles San Francisco Chicago

2004N-0184

C5

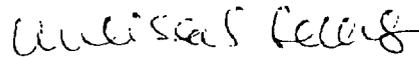
- a. Many companies such as Phillips have HACCP certified individuals on staff that are qualified and trained to handle a wide variety of food safety tasks, including the collection of samples.
 - b. The costs for outside sampling services are high. Currently, an outside service charges \$70-\$80 per hour. Our own personnel understand the legal requirements for sampling, and we believe it is a huge unnecessary cost to retain outside sampling services for all enforcement actions.
3. We also believe that many companies have the infrastructure to conduct their own testing in response to an FDA enforcement action, provided they follow the appropriate laws and regulations. Thus, Section 59.105 should be amended to mirror the requirements for private laboratories.
 4. Proposed 59.301(b) requires that private laboratories include, as part of the analytical package sent to the FDA an affidavit stating
 - a. It is not aware of any other tests being performed on the lot; or
 - b. The name and address of the person conducting the other tests.

We believe that this requirement is extremely burdensome and unnecessary. It will involve additional work on the part of the lab and therefore additional costs to the importer

5. Proposed 59.301(c) requires maintaining records for three years after submitting the analytical package and original sample collection report to the FDA. We believe that the records should only have to be maintained for two years, which is consistent with related FDA records retention schedules.
6. Finally, we are concerned about the general direction that the FDA is taking with respect to sampling. Recently, we have noticed a significant increase in FDA requests for us to provide independent proof that a product is safe for human consumption, as opposed to making the product available for FDA's own in-house testing. The costs to retain an outside lab to perform these samples can be as high as \$10,000 per action, plus the loss of the product.

We appreciate the opportunity to provide comments and would be pleased to answer any questions or provide further information as requested.

Yours sincerely,


Melissa S. Sellers
General Counsel



1215 E. Fort Avenue
 Baltimore, MD 21230
 Phone: 443.263.1200
 Toll Free: 888.234.CRAB
 Fax: 410.837.8526
 www.phillipsfoods.com

Fax

To: FOA From: Melissa Secor S
 Fax: 301-807-6870 Pages: 3
 Phone: _____ Date: 7/28/04
 Re: Docket # 2002N-0085 CC: _____

- Urgent For Review Please Comment Please Reply Please Recycle
