

on hold, prior notice submitter, the importer, owner, or ultimate consignee may submit a written request asking FDA to review whether the foreign facility is subject to the requirements of section 415 of the FD&C Act. The interim final rule also sets out procedures and timeframes for this review process.

f. *Export after refusal (§ 1.285(f))*. A food under hold may be exported with CBP concurrence and supervision.

g. *No registration or request for review (§ 1.285(g))*. If no registration number is obtained from FDA or no request for FDA review is submitted in a timely fashion after a food is placed under hold, the food will be dealt with as set forth in CBP regulations relating to general order merchandise. It may only be sold for export or destroyed as agreed to by CBP and FDA.

h. *International mail (§ 1.285(k))*. In the case of food arriving by international mail, if required registration is lacking, the article will be held by CBP for 72 hours for FDA inspection and disposition. If the food is held and there is a return address, the parcel may be returned to sender. If there is no return address or the article of food in the parcel appears to present a hazard, the FDA may dispose of or destroy it, at FDA's expense. If FDA does not respond within 72 hours of the CBP hold, CBP may return the parcel to the sender or, if there is no return address, destroy the parcel at FDA's expense.

i. *Food carried by or otherwise accompanying an individual (§ 1.285(h))*. If placed on hold, the individual may arrange to have the food held at the port or exported. If such arrangements cannot be made, the food may be destroyed.

j. *Post-refusal and post-hold submissions (§ 1.285(i))*. To resolve a refusal if an article of food has been refused under § 1.285(a), the facility must be registered and a registration number obtained from FDA. The prior notice must then be submitted in accordance with § 1.283(c).

To resolve the hold if an article of food is held under § 1.285(b) the foreign facility must be registered and a registration number obtained from FDA. FDA must be notified of the applicable registration number in writing by mail, express courier, fax, or e-mail. The notification must provide the name and contact information for the person providing the registration information. The location for delivering this notification will be listed at <http://www.fda.gov>—see Food Facility Registration. If FDA determines that the food should no longer be held, it will notify the person providing the

information and CBP the food is no longer subject to hold under section 801(l).

k. *Prohibition on delivery outside of the port (§ 1.285(l))*. An article of food under hold may not be delivered to the importer, owner, or ultimate consignee or transferred by any person from the port or the secure facility until registration is complete and FDA has notified CBP that the article of food is no longer under hold.

l. *Relationship to other admissibility provisions (§ 1.285(m))*. A determination that an article of food is no longer subject to hold under section 801(l) of the FD&C Act is different than, and may come before, determinations of admissibility under other provisions of the FD&C Act or other U.S. laws. A determination that an article of food is no longer subject to hold under section 801(l) does not mean that it will be granted admission under other provisions of the FD&C Act or other U.S. laws.

IV. Issuance of an Interim Final Rule and Effective Date; Comments

We are issuing this rule as an interim final rule, with an opportunity for public comment. Although we are seeking comment on this interim final rule, it will be in effect on December 12, 2003. Thus, its requirements will be in effect and have the force and effect of law from that date until they are modified by the issuance of a final rule. FDA will, however, provide guidance on enforcement to its staff containing the agency's policies on injunctions, prosecution, and debarment related to failure to provide timely and accurate prior notice, as well as the agency's policies regarding refusals under section 801(m)(1) of the FD&C Act and holds under section 801(l). FDA intends to include a transition period in this guidance, during which it will emphasize education to achieve compliance. While FDA will nonetheless be authorized to take various types of enforcement action for violations of the prior notice requirements, this planned transition period will allow FDA to focus its resources on the most appropriate circumstances.

The comment period on this interim final rule will open today for a period of 75 days. Moreover, to ensure that those that comment on this interim final rule have had the benefit of our outreach and educational efforts and have had experience with the systems, timeframes, and data elements, FDA intends to reopen the comment period for an additional 30 days in March 2004. In addition, this date will coincide with

the issuance of the plan by FDA and CBP relating to timeframes.

FDA invites public comment on this interim final rule. The agency will consider modifications to this interim final rule based on comments made during the comment period. Interested persons may submit to the Division of Dockets Management (*see ADDRESSES*) written or electronic comments regarding this interim final rule by [75 days after December 12, 2003.]. Two copies of any comments are to be submitted, except that individuals may submit one copy. Submit one electronic copy. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

As noted, this regulation is effective on December 12, 2003. FDA will address comments received and confirm or amend the interim final rule in a final rule. The agency, however, will not consider any comments that have been previously considered during this rulemaking.

V. Analysis of Economic Impacts

A. Final Regulatory Impact Analysis

FDA has examined the economic implications of this interim final rule as required by Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including: Having an annual effect on the economy of \$100 million, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues. FDA has determined that this interim final rule is a significant regulatory action as defined by Executive Order 12866.

Comments on the economic analysis of the proposed prior notice rule covered several major issues, including: The costs estimated to learn the rule, the costs to coordinate prior notice information, the costs of filing through a broker, and the costs of delayed arrival (including truck time costs and the costs