

appeal is filed, after providing opportunity for an informal hearing, the Secretary must confirm or terminate the detention order. The appeal process terminates if the Secretary institutes an action for seizure or injunction regarding the article of food involved. Confirmation of a detention order is considered a final agency action.

• *Prohibited act:* Amends section 301 of the act making it a prohibited act to transfer a detained article of food in violation of a detention order, or to remove or alter any mark or label required by the detention order to identify the article of food as detained.

Section 303 of the Bioterrorism Act also includes a provision authorizing temporary holds at ports of entry that will not be addressed in this proposed regulation, but through separate guidance that FDA plans to develop and issue. The temporary hold provision authorizes FDA to request the Secretary of Treasury to institute a temporary hold for up to 24 hours on an article of food offered for import at a U.S. port of entry if FDA has credible evidence or information indicating that an article of food presents a threat of serious adverse health consequences or death to humans or animals, and FDA is unable immediately to inspect, examine, or investigate such article. FDA has received comments on the temporary hold provision in the public docket (Docket No. 02N-0275). FDA plans to consider these comments in developing guidance on the temporary hold provision.

FDA is proposing to amend title 21 of the Code of Federal Regulations (CFR) by establishing a new subpart to part 1 (21 CFR part 1) consisting of subpart K entitled "Administrative Detention of Food for Human or Animal Consumption." In this proposed rule, we describe the procedures for how FDA will detain an article of food and the process for appealing a detention order. We also address procedures for instituting on an expedited basis certain enforcement actions with respect to detained perishable foods. This proposed rule also makes a conforming amendment to part 16 (21 CFR part 16) entitled "Regulatory Hearing Before the Food and Drug Administration." Although the statutory requirements in section 304(h) of the act are self-executing and are currently in effect, FDA is issuing this regulation to further refine aspects of the administrative detention requirements.

The administrative detention process described in this proposed rule is modeled after FDA's medical device administrative detention regulation found at § 800.55 (21 CFR 800.55). FDA

believes that this process has been effective and efficient for medical device administrative detentions and should also work well for administrative detentions of food. In addition, using the medical device regulations as a model will be helpful to the agency as field offices are familiar with this detention process and training will not need to be as extensive.

Section 303 of the Bioterrorism Act provides for an opportunity for an informal hearing as part of the appeal process. The regulations in part 16 set out FDA's informal hearing procedures and provide that its procedures apply when the act or FDA regulations provide for an opportunity for a hearing and no specific hearing regulations exist (see § 16.1(b)). Proposed § 1.403 states that any informal hearing held on an appeal of a detention order will be conducted in accordance with part 16 except as noted therein.

Although section 303 of the Bioterrorism Act requires FDA only to promulgate regulations establishing procedures for instituting on an expedited basis certain enforcement actions against perishable food subject to a detention order, FDA also is proposing in this regulation to describe the procedures for how FDA will detain both perishable and nonperishable articles of food and the process for appealing a detention order. If FDA did not establish other requirements for the process for appealing a detention order in this proposed regulation, it would be difficult for FDA to meet certain requirements in section 303 of the Bioterrorism Act. For example, section 303 of the Bioterrorism Act requires FDA, after providing an opportunity for an informal hearing, to confirm or terminate a detention order within 5 days after the date of appeal. Two of the requirements in this proposed rule would be to impose a deadline for filing an appeal and a limitation on the length of the informal hearing (see proposed §§ 1.402 and 1.403). These proposed requirements are intended to ensure that FDA meets section 303's timing requirements. FDA is proposing to codify the procedures for how FDA will detain an article of food to clarify our procedures for the public and to follow FDA's model for the administrative detention of medical devices that has its procedures codified at 21 CFR 800.55. FDA is proposing to incorporate these provisions in a regulation instead of a guidance document to make them enforceable since guidance documents are not binding.

FDA wants to make clear that this proposed rule does not implement section 801 of the act (21 U.S.C. 381),

despite its use of the term "detention". As explained in this preamble, this proposed rule implements section 303 of the Bioterrorism Act, which amends section 304 of the act. This amendment grants FDA the authority to detain food upon credible evidence or information of a threat of serious adverse health consequences or death to humans or animals. FDA has had similar authority for medical devices under section 304(g) of the act since 1976, and usually refers to this authority as "administrative detention" (§ 800.55). Section 801(a) of the act provides that FDA shall refuse the admission of any article of food that has been imported or offered for import that appears, among other things, to be adulterated or misbranded under the act, based on physical examination or otherwise. Under section 801(a), before FDA refuses admission to an article that appears violative, importers are provided with a notice of hearing on refusal of admission, which notifies them that the article may be subject to refusal of admission, and provides them with an opportunity to introduce testimony and establish that the article is fully in compliance with the act (§ 1.94). FDA refers to this administrative process concerning imports as detention (see "FDA Regulatory Procedures Manual" (RPM), chapter 9). Because of the authorities available to FDA and the U.S. Customs Service to control imported food subject to section 801(a) of the act, FDA does not expect to frequently use administrative detention under section 303 of the Bioterrorism Act to control such imported food.

Section 304(h) of the act, as added by section 303 of the Bioterrorism Act, provides that:

An officer or qualified employee of the Food and Drug Administration may order the detention, in accordance with this subsection, of any article of food that is found during an inspection, examination, or investigation under this Act conducted by such officer or qualified employee, if the officer or qualified employee has credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals.

This language does not include a limitation similar to that in section 304(g) of the act that provides for administrative detentions of devices during inspections conducted under section 704 of the act, a provision of the act that has an interstate commerce component. In addition, the prohibited act related to administrative detention of food, section 301(bb) of the act, unlike some other prohibited acts in section 301, does not include an interstate commerce component.