infections. The supplemental NADA provides for expanding the use for the treatment and control of an additional adult hookworm infection.

EFFECTIVE DATE: November 20, 1996.

FOR FURTHER INFORMATION CONTACT: Marcia K. Larkins, Center for Veterinary Medicine (HFV–112), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–0614.

SUPPLEMENTARY INFORMATION: Merck Research Laboratories, Division of Merck & Co., Inc., P.O. Box 2000, Rahway, NJ 07065, filed supplemental NADA 140–971, which provides for the use of Heartgard™ Plus (ivermectin with pyrantel pamoate) in dogs for the treatment and control of adult hookworm *Ancylostoma braziliense* infections. The product is used to prevent canine heartworm disease by eliminating the tissue stage of heartworm larvae *Dirofilaria immitis* for 1 month (30 days) after infection, and for the treatment and control of adult ascarids *Toxocara canis* and *Toxascaris leonina*, and adult hookworms *A. caninum*, *Uncinaria stenocephala*, and *A. braziliense*. The product is limited to use by or on the order of a licensed veterinarian. The supplement is approved as of October 3, 1996, and the regulations are amended in 21 CFR 520.1196(c)(1)(ii) to add treatment and control of adult hookworm *A. braziliense*. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act, this supplemental NADA qualifies for a 3-year marketing exclusivity period beginning October 3, 1996, because it contains reports of new clinical or field investigations essential to the approval and conducted or sponsored by the applicant. The exclusivity period applies only to the added claim for treatment and control of adult hookworm *A. braziliense*.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 520.1196 [Amended]

2. Section 520.1196 *Ivermectin and pyrantel pamoate chewable tablet* is amended in paragraph (c)(1)(ii) by adding the name ''*, A. braziliense,*'' after ''*Ancylostoma caninum*''.

Dated: October 29, 1996.

Andrew J. Beaulieau,

Deputy Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 96–29631 Filed 11–19–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 810

[Docket No. 93N–0260]

Medical Device Recall Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is establishing procedures for implementing the medical device recall authority provided in the Safe Medical Devices Act of 1990 (the SMDA). This statutory authority protects the public health by permitting FDA to remove dangerous devices from the market promptly. This authority complements other provisions of the device law, including tracking and notification.

DATES: The regulation is effective May 19, 1997.

Written comments on the information collection requirements should be submitted by January 21, 1997.

ADDRESSES: Submit written comments on the collection of information requirements to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: John H. Samalik, Center for Devices and Radiological Health (HFZ–323), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4703.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of June 14, 1994 (59 FR 30656), FDA published a proposed rule to establish the procedures it will follow in exercising its medical device recall authority provided in the SMDA. Interested persons were given until September 12, 1994, to comment on the proposed regulation. FDA received a total of nine comments from an infant ventilator manufacturer, a regulatory consulting corporation, an electrical manufacturers association, a medical device manufacturers association, a manufacturer of in vitro diagnostic products, and four other medical device companies.

II. Summary of the Final Rule

Section 8 of the SMDA (Pub. L. 101–629) amends section 518 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360h) by adding a new subsection (e) entitled ''Recall Authority.'' Section 518(e)(1) of the act provides that, if FDA finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, FDA shall issue an order requiring the appropriate person to immediately cease distribution of the device, immediately notify health professionals and device user facilities of the order, and instruct such professionals and facilities to cease use of the device. Section 518(e)(2) of the act states that, after providing an opportunity for an informal hearing, FDA may amend the cease distribution and notification order to require a recall of the device.

Section 502(t) of the act (21 U.S.C. 352(t)) provides that a device is misbranded if there is a failure or refusal to comply with any requirement prescribed under section 518 of the act respecting the device. Section 301(q)(1) of the act (21 U.S.C. 331(q)(1)) makes the failure or refusal to comply with any requirement prescribed under section 518 of the act, or the causing thereof, a prohibited act. A person subject to a cease distribution and notification order or a mandatory recall order issued

under section 518(e) of the act under these regulations, and who fails or refuses to comply, may therefore be subject to regulatory actions by FDA.

Prior to issuing a cease distribution and notification order, FDA will conduct a Health Hazard Evaluation which will take into account the following factors: (1) Whether any disease or injuries have already occurred from the use of the product; (2) whether any existing conditions could contribute to a clinical situation that could expose humans or animals to a health hazard; (3) the hazard to various segments of the population who are expected to be exposed to the product being considered; (4) the degree of seriousness of the health hazard to which the populations at risk would be exposed; (5) the likelihood of occurrence of the hazard; (6) the consequences of occurrence of the hazard; as well as (7) the risk of ceasing distribution of the device as compared with the risk of not ceasing distribution of the device by considering, for example, the availability of alternate medical devices.

Under new § 810.11(a), the person named in a cease distribution and notification order may submit a written request to FDA for a regulatory hearing within the timeframe specified in the order, which, generally, will not be less than 3 working days after receipt of the order. (Throughout the preamble and the regulation the term ''regulatory hearing'' references the ''informal hearing'' under section 518(e) of the act.) According to § 810.11(b), if a request for a regulatory hearing is granted, the regulatory hearing is limited to reviewing the actions which prompted issuance of the cease distribution and notification order and determining if FDA should affirm, modify, or vacate the order or amend the cease distribution and notification order to require a recall of the device that was the subject of the order. The hearing may also address the actions that might be required by a recall order, including an appropriate recall strategy, if FDA later orders a recall.

Under § 810.11(c), if a request for a regulatory hearing is granted, the regulatory hearing will be conducted in accordance with the procedures set out in section 201(x) of the act (21 U.S.C. 321(x)) and part 16 (21 CFR part 16). After a regulatory hearing commences, the presiding officer may issue a summary decision on any issue if he or she determines that there is no genuine and substantial issue of fact respecting that issue. Under § 810.11(e), the presiding officer will ordinarily hold any regulatory hearing under § 810.11(a) no fewer than 2 working days after receipt of the request for a hearing and no later than 10 working days after the date of issuance of the cease distribution and notification order. However, FDA and the person named in the order may agree to a later date or the presiding officer may determine that the hearing should be held in fewer than 2 days. The presiding officer shall provide the requestor written notification of the agency's decision to affirm, modify, or vacate the order or amend the cease distribution and notification order to require a recall of the device within 15 working days after conducting a regulatory hearing.

Under § 810.12(a), in lieu of requesting a regulatory hearing under § 810.11, the person named in the cease distribution and notification order may submit a written request to FDA asking that the order be modified or vacated. Such request must be submitted within the timeframe specified in the cease distribution and notification order, unless FDA and the person named in the order agree to a later date. In most cases, FDA will specify that a written request for review of a cease distribution and notification order must be submitted to the agency within 10 working days of issuance of the cease distribution and notification order, but generally not less than 3 working days after receipt of the order. According to § 810.12(c), the agency official who issued the cease distribution and notification order shall provide the requestor written notification of the decision of the agency to affirm, modify, or vacate the order or amend the cease distribution and notification order to require a recall of the device within 15 working days of receipt of the written request.

According to § 810.13(a), if the person named in a cease distribution and notification order does not request a regulatory hearing or submit a request for agency review of the order, or, if after conducting a regulatory hearing or completing agency review of a cease distribution and notification order under § 810.11 or § 810.12, FDA determines that the order should be amended to require a recall of the device with respect to which the order was issued, FDA shall amend the order to require such a recall. FDA shall amend the order to require such a recall within 15 working days of issuance of a cease distribution and notification order if a regulatory hearing or agency review of the order is not requested or within 15 working days of conducting a regulatory hearing under § 810.11 or completing agency review of a cease distribution and notification order under § 810.12.

According to § 810.14(a), the person named in a cease distribution and notification order shall comply with the order, which FDA will fashion as appropriate for the individual circumstances of the case. The person named in a cease distribution and notification order modified under § 810.11(e) or § 810.12(c) or a mandatory recall order issued under § 810.13 shall develop a strategy for complying with the order that is appropriate for the individual circumstances. Under § 810.14(b)(1), the person named in the cease distribution and notification order modified under § 810.11(e) or § 810.12(c) or a mandatory recall order shall submit a copy of the proposed strategy to the agency within the timeframe specified in the order. Under § 810.14(b)(2), the agency will review the proposed strategy and make any changes to the strategy that it deems necessary within 7 working days of receipt of the proposed strategy. The person named in the cease distribution and notification order or mandatory recall order shall act in accordance with a strategy determined by FDA to be appropriate.

Under § 810.15(a), the person named in a cease distribution and notification order or a mandatory recall order is responsible for promptly notifying each health professional, user facility, consignee, or individual, as appropriate, of the order.

Under § 810.16(a), the person named in a cease distribution and notification order or a mandatory recall order shall submit periodic status reports to FDA to enable the agency to assess the person's progress in complying with the order.

Under § 810.17, the person named in a cease distribution and notification order or a mandatory recall order may request termination of the order by submitting a written request to FDA. FDA may terminate a cease distribution and notification order or a mandatory recall order when the agency determines that the person named in the order has taken all reasonable steps to ensure that all health professionals, device user facilities, consignees, and, where appropriate, individuals have been notified of the cease distribution and notification order and have complied with the instructions to cease use of the device; and that the person named in the order has removed the device from the market or has corrected the device so that use of the device would not cause serious, adverse health consequences or death. FDA will respond to a written request for termination of a cease distribution and

notification or recall order within 30 working days of its receipt.

Under § 810.18, the agency will make available to the public in the weekly FDA Enforcement Report a descriptive listing of each new mandatory recall issued under § 810.13.

III. Relationship Between Temporary Suspension of Approval of a Premarket Approval Application (PMA) or PMA Supplement and Medical Device Recall Authority

The SMDA provided FDA with, among other things, the authority to issue orders to temporarily suspend the approval of a PMA or a PMA supplement and to recall medical devices.

Section 9 of the SMDA amends section 515(e) of the act (21 U.S.C. 360e(e)) by adding section 515(e)(3) of the act which provides the agency with the authority to temporarily suspend approval of a PMA. This authority applies to the original PMA, as well as to any PMA supplement(s), for a medical device. Section 515(e)(3) of the act and 21 CFR 814.47, the implementing regulation, provide the agency with a quick method of removing dangerous devices from the market pending resolution of permanent PMA or PMA supplement withdrawal proceedings.

The agency's authority to temporarily suspend approval of a PMA and/or its PMA supplements may be invoked when FDA wants a manufacturer to remove from the market the class III device that was approved under the subject PMA or PMA supplement, pending permanent withdrawal of approval of the PMA and/or PMA supplements. On the other hand, FDA's medical device recall authority may be invoked, for example, when FDA wants an individual to cease distribution and/or recall certain lots, batches, models, or complete product lines of class I, class II, or class III devices that have been introduced into commerce until such devices are brought into compliance.

The threshold criteria are identical for invoking the medical device recall authority and the authority to temporarily suspend approval of a PMA or PMA supplement. FDA may issue an order under either one of these authorities only when FDA has invoked that authority and has determined under that authority that there is a reasonable probability that continued distribution of a device would cause serious, adverse health consequences or death. Furthermore, under both authorities, FDA must provide the person subject to the order and the holder of the approved PMA or PMA supplement for the device with an opportunity for a regulatory hearing. In both situations, if a request for a regulatory hearing is granted, the regulatory hearing is to be conducted by FDA under part 16.

The agency may invoke either its medical device recall authority or its authority to temporarily suspend approval of the PMA and/or PMA supplements for a class III device or both at once. If both authorities are invoked, and if regulatory hearings are requested and granted with respect to each one, the medical device recall regulatory hearing will be combined with the temporary suspension of approval of a PMA and/or PMA supplements regulatory hearing. This combined regulatory hearing will occur after FDA makes the requisite finding, issues a cease distribution and notification order, and issues a letter of intent to temporarily suspend approval of a PMA and/or PMA supplements. This combined regulatory hearing will not eliminate the PMA and/or PMA supplements holder's opportunity for a regulatory hearing prior to permanently withdrawing approval of a PMA and/or PMA supplements. (See section 515(e)(1) of the act.)

IV. Summary and Analysis of Comments and FDA's Responses

A. General Comments

1. Various comments noted the absence of formal deadlines for the following: Issuance of a cease distribution and notification order (proposed § 810.10(a)); completion of a regulatory hearing (proposed § 810.11(e)); receipt of a written request for review of a cease distribution and notification order (proposed § 810.12(c)); issuance of a mandatory recall order (proposed § 810.13(a)); amending a cease distribution and notification order to include a mandatory recall order after an initial determination that a recall is not necessary (proposed § 810.13(e) deleted in the final regulation); review and acceptance of a cease distribution and notification of mandatory recall strategy prior to initiating the strategy (proposed § 810.14(a)(7), renumbered as § 810.14(b)(2) in the final regulation); and receipt of a request for termination of a cease distribution and notification order or a recall order (proposed § 810.17(c)).

The comments requested deadlines for these actions. Moreover, the comments requested that FDA automatically vacate cease distribution and notification orders, mandatory recall orders, and/or strategies in the absence of FDA action within a fixed number of days. According to these comments, the absence of deadlines creates the possibility that such orders will become a preliminary or permanent injunction in those situations where FDA is slow in completing its deliberations.

Two other comments stated that the absence of such deadlines is inconsistent with the congressional intent that ''the hearing be analogous to a hearing on a temporary restraining order'' (TRO). According to these comments, hearings commenced under a TRO occur prior to the issuance of a TRO, and TRO's remain in effect for a limited time period not to exceed 10 days while the court decides whether or not to issue a preliminary injunction.

FDA agrees that timeframes for certain agency actions in the recall context would be useful.

FDA will be given 15 working days to complete its deliberative process following the completion of a regulatory hearing (§ 810.11(e)) or receipt of a written request for review of a cease distribution and notification order (§ 810.12(c)). Accordingly, under § 810.13(a), FDA will amend a cease distribution and notification order to include a mandatory recall within 15 working days of issuance of the cease distribution and notification order if a regulatory hearing or agency review of the order is not requested, within 15 working days of denying a request for a hearing, or within 15 working days after conducting a regulatory hearing under § 810.11 or receiving a written request for review of a cease distribution and notification order under § 810.12.

FDA has omitted proposed § 810.13(e) from the final rule. Therefore, there is no need to consider establishment of a deadline for this section.

Under § 810.14(b)(2), the agency will review and amend, reject, or accept a proposed strategy for a cease distribution and notification order modified under § 810.11(e) or § 810.12(c) or a mandatory recall within 7 working days of receipt of such a strategy.

As suggested by the legislative history, under § 810.17(c), FDA will respond to a written request for termination of a cease distribution and notification or recall order within 30 working days of its receipt. (See S. Rept. 513, 101st Cong., 2d. sess. 37 (1990).)

FDA believes it is unnecessary to establish a deadline under § 810.10(a) because until FDA issues a cease distribution and notification order the firm may continue to distribute medical devices. Therefore, under this section, FDA's failure to act within a specified

timeframe would not affect a company's ability to distribute products.

In the interest of public health, FDA disagrees that it should automatically vacate cease distribution and notification orders, mandatory recall orders, and/or strategies if FDA fails to act within the number of days specified for the various actions above. Moreover, the agency disagrees with the comments that stated that formal deadlines are needed because Congress analogized the regulatory hearing to a judicial hearing on a TRO. The point of Congress' analogy to TRO's is that the agency should be able, when needed, to provide notice, hold the regulatory hearing, and issue its decision in a single day. (See H. Rept. 808, 101st Cong., 2d sess. 29 (1990).) That is, Congress intended to permit the agency to act quickly, but it did not intend to require the agency to do so.

2. A comment requested that the rule be modified to include examples and/or more specific standards or factors to be met before a cease distribution and notification or mandatory recall occurs, which would ensure consistency among such decisions.

In drafting the SMDA, both the House of Representatives and the Senate focused on the implementation and enforcement of section 518 of the act since its enactment in the Medical Device Amendments of 1976 (Pub. L. 94–295) (the amendments). (See 59 FR 30656, June 14, 1994.) Section 518 of the act authorizes FDA to require notification of a risk to health presented by a medical device, or to require repair, replacement, or refund of the purchase price of a device. The House of Representatives noted that under section 518(b) of the act:

> [E]ven when the FDA has discovered a serious health hazard associated with a medical device, the Agency faces a unique barrier to enforcing important administrative remedies. Unlike other health and safety agencies, FDA may not take administrative action to order a defective device recalled unless it can show that the device did not meet the state-of-the-art at the time it was designed and manufactured.

(H. Rept. 808, 101st Cong., 2d sess. 14 (1990))

Furthermore, the Senate found that ''[T]he 'repair, replacement, or refund' provisions of section 518(b) of the Act have never been used. Section 518(b)'s intricate findings and procedures have served as an inappropriate deterrent to its use.'' (See S. Rept. 513, 101st Cong., 2d sess. 19 (1990).) Based on these findings, Congress determined that a more simplified and strengthened recall authority was needed. Thus, Congress explicitly stated that, under the new recall authority, FDA ''will have considerable discretion in determining whether it is more likely than not that the continued distribution of a device would cause serious, adverse health consequences or death.'' (See S. Rept. 513, 101st Cong., 2d sess. 19 (1990).)

As the agency explained in the proposed rule:

> The mandatory recall authority in section 518(e) of the act complements existing provisions in sections 518(a), (b), and (c) of the act. Section 518(e) provides that, if FDA finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, FDA may order the appropriate person(s) to immediately cease distribution of the device, to immediately notify health professionals and device user facilities of the order, and to instruct such professionals and facilities to cease use of the device. Section 518(e) of the act also states that, after providing an opportunity for an informal hearing, FDA may amend the cease distribution and notification order to require a recall of the device. This new authority protects the public health by permitting FDA to ensure the prompt removal of dangerous and defective devices from the market.

59 FR 30656. Under this provision, therefore, the agency has the discretion both to invoke the provision and, once the provision is invoked and appropriate findings are made, to exercise discretion regarding issuance of any orders under this provision.

While having necessary discretion under this provision, FDA also recognizes that it is important to exercise that discretion judiciously. Accordingly, under 21 CFR 5.56, the Directors and Deputy Directors of the Center for Devices and Radiological Health (CDRH), the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), and the Directors and Deputy Directors of the Offices of Compliance of CDRH, CDER, and CBER are the FDA officials within these centers authorized to invoke section 518(e) of the act for medical devices assigned to their respective organizations. Limiting decisionmaking authority to these FDA headquarters officials will help to ensure consistent determinations regarding whether to issue such orders.

Moreover, for cease distribution and notification orders and recall orders, FDA interprets the standard in §§ 810.10(a) and 810.13 to match very closely the elements of a class I voluntary recall under part 7, subpart C (21 CFR part 7, subpart C), for which the agency has a long record of experience. Because FDA expects that most device manufacturers will voluntarily initiate a recall, it also expects that most serious health hazards associated with use of devices warranting a recall will continue to be handled under the voluntary recall guideline found in part 7, subpart C.

3. Several comments stated that the proposed rule fails to provide the individual named in the cease distribution and notification order with the following opportunities to be heard prior to issuance of the order: (a) To petition for a hearing prior to notification of customers of a cease distribution order; (b) to provide data and/or comments from their firm regarding the safety and effectiveness of the firm's device before a cease distribution and notification order is issued; (c) to provide for review by outside, experienced medical experts and/or clinicians who use the device; (d) to provide for open, informal communications between FDA and expert consultants prior to or in lieu of a cease distribution and notification order; (e) to discuss with FDA the basis for the cease distribution and notification order before taking action; or (f) to hold a hearing prior to the time when the individual subject to the order must take the specified actions, including notifying affected users.

Another comment noted that FDA's requirement that device user facilities must still be notified if a hearing is requested defeats the intent of section 518(e) of the act. According to the comment, it is meaningless to hold a hearing on the actions required by the order or for the Secretary to vacate the order if the person subject to the order already has taken the specified actions, including notification of affected users.

FDA agrees with the value of consulting with the device manufacturer prior to issuance of a cease distribution and notification order. Accordingly, FDA has amended § 810.10(a) to provide that before FDA makes the requisite finding that there is a reasonable probability that a device would cause serious, adverse health consequences or death, FDA will informally notify the appropriate individual of its tentative findings and provide the appropriate individual with an opportunity to consult with the agency. Because it may be necessary for the agency to act quickly to protect the public health, the extent of this consultation may be limited. The agency nevertheless expects that, typically, during this informal notification stage the individual may provide FDA with data and/or comments regarding the safety and effectiveness of the device, may provide review by outside, experienced medical experts, may solicit communications from expert consultants, and/or may discuss the basis of the order with FDA. During this

stage, FDA will provide the appropriate individual with an opportunity to convince FDA that there is no basis for the agency to make the requisite finding, or, alternatively, for that appropriate individual to conclude that the device should be voluntarily recalled.

If the appropriate person convinces FDA that there is no basis for making the finding that there is a reasonable probability that a device would cause serious, adverse health consequences or death or that the appropriate person has acted responsibly in conducting an adequate voluntary recall, FDA will not likely make such a finding. However, if the appropriate person fails to convince FDA that there is no basis for such a finding or fails to act responsibly in conducting an adequate voluntary recall, the agency will make the requisite finding. In either case, the individual is provided with an opportunity to challenge FDA's tentative findings before the agency adopts them.

Moreover, under the legislative history of the medical device recall authority, individuals must immediately notify customers and cease distribution under an order, after which the opportunity for a hearing follows:

> The conference agreement requires the Secretary, after making an appropriate finding, to issue an initial order providing for the immediate cessation and use of the device, with an informal hearing to follow within 10 days to determine whether to vacate the order or whether to amend the order to require a recall.

(H. Conf. Rept. 959, 101st Cong., 2d sess. 25 (1990))

FDA has interpreted this statement to mean that if a hearing is requested, the device still may not be distributed and health professionals and device user facilities must still be notified. (See 59 FR 30656 at 30657.)

4. Several comments implied that the medical device recall regulation needs to clarify the criteria for issuing mandatory recall orders.

A recall may occur only after FDA has done the following: (a) Made the requisite finding, (b) issued a cease distribution and notification order, (c) provided the person named in the cease distribution and notification order with an opportunity for a regulatory hearing, and (d) determined that a recall of a device from a device user facility will not present a greater health risk than the health risk of not recalling the device from use. Under the medical device recall regulation, FDA may amend a cease distribution and notification order to include a mandatory recall in three circumstances.

Under the first circumstance, FDA may amend a cease distribution and notification order to include a recall if the individual named in the cease distribution and notification order complies with the order and requests a regulatory hearing, but is unable to demonstrate that all devices subject to the order do not pose a reasonable probability of causing serious, adverse health consequences or death. If the individual named in the order is able to demonstrate that devices do not pose a reasonable probability of causing serious, adverse health consequences or death, then FDA will allow those devices to be distributed and used. Simultaneously, in accordance with section 518(e)(1) of the act, FDA will vacate the cease distribution and notification order for these devices because inadequate grounds exist to support the actions required by the cease distribution and notification order.

Under the second circumstance, FDA may amend a cease distribution and notification order to include a recall order if the individual named in the order does not comply with the order and does not request a regulatory hearing. FDA will issue a recall order to retrieve the devices that were shipped to wholesalers, retailers, or users contrary to the cease distribution and notification order when these devices continue to pose a reasonable probability of causing serious, adverse health consequences or death.

Under the third circumstance, FDA may amend a cease distribution and notification order to include a mandatory recall if the individual named in the order complies with the order and initiates a voluntary recall which is found to be ineffective, i.e., the devices subject to voluntary recall actions continue to pose a reasonable probability of causing serious, adverse health consequences or death. In this situation, FDA may amend the order to include a mandatory recall because the devices continue to pose a reasonable probability of causing serious, adverse health consequences or death.

In all the circumstances described above, FDA retains the authority to amend the cease distribution and notification order to include a recall order because the devices subject to the cease distribution and notification order continue to pose a reasonable probability of causing serious, adverse health consequences or death.

5. A comment stated that some FDA personnel would use proposed § 810.11(a) to establish unreasonable deadlines for requesting a regulatory hearing. The comment emphasized that FDA's regulations relating to regulatory hearings (§ 16.22(b)) specify that the manufacturer is to have a minimum of 3 working days to request a hearing. Thus, the comment recommended that the section be revised as follows: ''Any request for a regulatory hearing shall be submitted in writing to the agency employee identified in the order within the timeframe specified by FDA, which shall not be less than three working days.''

According to two comments, proposed § 810.11(e), which allows FDA to hold a regulatory hearing in less than 3 days from the date of notice of the order, provides inadequate notice and opportunity to prepare for an informal hearing, e.g., to prepare expert witnesses. Therefore, one of the comments suggested that special findings be required when FDA seeks to require a respondent to participate in a regulatory hearing in less than 10 days. Another comment suggested that the phrase ''no less than 5 days and no later than 10 days after receipt of the distribution and notification order'' be incorporated in this section. Another comment stated that proposed § 810.11(e) needs to be more clearly defined as to implementation, threshold for its use, level of approval needed for this action, and parameters within which it can be used given FDA's broad authority to require an immediate hearing under this section.

FDA agrees that § 810.11(a) and (e) should be revised to reference the regulatory hearing procedures set out in part 16. Thus, the agency has changed § 810.11(a) so that the person offered an opportunity for a hearing has the amount of time specified in the notice, which, in accordance with § 16.22(b), ordinarily will not be less than 3 working days after receipt of the notice, within which to request a hearing. Furthermore, under § 16.24(e), the agency has changed § 810.11(e) to require that a hearing ordinarily will not be held less than 2 working days after receipt of the request for hearing, if the request is granted. In accordance with § 16.60(h), the Commissioner of Food and Drugs or the presiding officer has the power under § 10.19 to suspend, modify, or waive any provision of this part. This possibility is reflected in the preamble to the proposed rule, which, based on the legislative history, states: ''Where warranted, * * * FDA may require that the hearing request be submitted in less than 3 days, possibly even on the same day on which the person receives the order.'' (See 59 FR 30656 at 30657 and 30658 (citing H. Rept. 808, 101st Cong., 2d sess. 29 (1990)).)

Given the revisions stated above, FDA disagrees that proposed § 810.11(e)

needs to be more clearly defined as to implementation, threshold for its use, level of approval needed for this action, or parameters within which it can be used. In all but the most extreme circumstances, FDA does not intend to exercise its authority to hold an immediate hearing under § 810.11(e).

6. Several comments requested rephrasing proposed § 810.3, which relates to computation of time. One comment suggested that it be rephrased using the term calendar days. Another comment suggested that this section be revised as follows:

> In computing any period of time prescribed or allowed by this part, the day of the act or event from which the designated period of time begins to run shall not be included. All other calendar days, including Saturday and Sunday shall be included. Federal legal holidays shall be excluded.

According to this comment, there is no need to build a ''weekend and weather'' allowance into the regulation because FDA has in the past exercised its judgment when manufacturers have made good faith efforts.

A comment noted that under proposed § 810.11(a), the requirement that a request for a hearing be submitted to FDA within 3 days of receipt of FDA's cease distribution and notification order could collapse into 1 working day if the order is received on a Friday and the computation of time defined in proposed § 810.3 is used. To remedy this problem, the comment requested that FDA either: (a) Change the computation of time method to working days and retain the 3-day period or (b) change the period to 5 days and retain the computation of time as calendar days.

FDA agrees that the computation of time needs to be revised and has changed the computation of time method to working days. Accordingly, FDA has omitted the ''weekend and weather allowance'' in § 810.3.

7. Two comments recommended that proposed § 810.10(d)(9) be eliminated because it is both inappropriate and outside FDA authority to delegate to manufacturers the enforcement responsibility of providing to the agency information respecting the names and addresses of health professionals or device user facilities that are not in compliance with the notification instructions. Another comment stated that this section will result in FDA intruding into the practice of medicine.

FDA believes that it is not necessary to include proposed § 810.10(d)(9) in the regulation and has deleted that provision from the final regulation.

8. A comment stated that in the preamble of the proposed rule, FDA notes that the informal hearing is analogous to a TRO. According to this comment, although FDA makes this analogy, FDA fails to note that generally persons subject to a TRO are not required to act before the hearing. Rule 65(b) of the Federal Rules of Civil Procedure states that a TRO may be granted before the adverse party or his attorney can be heard in opposition only if ''immediate and irreparable injury, loss, or damage will result'' if the restraining order is not granted. Accordingly, the comment maintained that in order for FDA to support a claim that action is required prior to the informal hearing, FDA must demonstrate such immediate and irreparable injury, loss, or damage. Moreover, this comment noted that the object of a TRO is to ''preserve the status quo.'' Requiring the person subject to a cease distribution and notification order to proceed with the actions required by the order, before he or she has an opportunity to present the case as to why the order is inappropriate, defeats, rather than preserves, the status quo.

FDA disagrees with this comment because it misinterprets the legislative history, which does not include an analogy between a cease distribution and notification order and a TRO. Rather, it includes an analogy between the recall order and a TRO, and the act and the regulation both provide for a regulatory hearing before FDA issues a recall order. Moreover, the analogy is directed at the quick judicial process for TRO's, which ''can result in notice, a hearing and a judicial decision in a single day.'' (See H. Rept. 808, 101st Cong., 2d sess. 29 (1990).)

9. Two comments contended that, in a number of instances, the language set forth in the preamble is inconsistent with the statutory language set forth in the SMDA. Specifically, the comments noted the following:

(a) The preamble to the proposed rule states that: ''The SMDA includes provisions designed to expand and strengthen FDA's authority to * * * remove dangerous *and defective* devices from the market promptly.'' (See 59 FR 30656 (emphasis added).) According to this comment, the phrase ''and defective'' does not appear in section 8 of the SMDA, which establishes the agency's mandatory recall authority. Thus, the comment recommended eliminating the qualifying phrase ''and defective'' from the discussion involving mandatory recalls.

FDA notes that the term ''dangerous and defective devices'' referred to by the comment was used in the preamble to the proposed rule with regard to FDA's new authority under the SMDA in general, not just FDA's new authority under section 8 of the SMDA for mandatory recalls. More importantly, under section 8 of the SMDA, the standard for issuance of a cease distribution and notification order applies to device hazards generally, whether the devices are dangerous and/or defective, provided that they present a reasonable probability of causing serious, adverse health consequences or death.

(b) The preamble also states that section 518 of the act ''authorizes FDA to require notification of a risk to health presented by a medical device.'' (See 59 FR 30656 (emphasis added).) According to this comment, the language set forth in section 518 of the act refers to an ''unreasonable risk of substantial harm,'' and not a ''risk to health'' presented by a medical device. Therefore, the comment recommended that FDA adopt the language ''unreasonable risk of substantial harm,'' in order to be consistent with section 518 of the act.

FDA notes that the preamble to the proposed rule clearly stated that the remedies provided in section 518(a), (b), and (c) of the act are available when the agency has determined that the device presents an unreasonable risk of substantial harm to the public health.

(c) In the preamble to the proposed rule, FDA reserved the right to amend a cease distribution and notification order to the status of mandatory recall order following a finding of inadequate compliance with the cease distribution and notification order or a finding that the voluntary recall actions are inadequate to eliminate the risk without providing the manufacturer an opportunity for an informal hearing. Several comments contended that it is inappropriate and contrary to Congressional intent to provide the agency with such broad discretion relative to amending a cease distribution and notification order.

In response to these comments, FDA has omitted § 810.13(e) from the final rule.

(d) One comment requested that the preamble to the final rule make clear that the purpose of the regulatory hearing is not merely to determine if a cease distribution order should be revised to require a recall, but also to determine if the cease distribution order should be otherwise amended or vacated. This revision would make the language set forth in the preamble consistent with the language set forth in section 518(e) of the act, as well as the language set forth in § 810.11(b)(1) of the proposed rule.

The final regulation has been revised to state that the purpose of the

regulatory hearing is to determine whether the order should be affirmed, modified, or vacated, or amended to require a mandatory recall of the device. (See § 810.11(b).)

10. A comment alleged that the regulation would limit the ability of responsible and well-meaning companies to act independently to protect the public health in the face of an ill conceived recall action.

FDA disagrees. In addition to the informal consultation prior to the issuance of a cease distribution and notification order, the regulatory hearing provided for in § 810.11(a) is the forum in which the individual named in the cease distribution and notification order can show that the cease distribution and notification order was ill conceived. After the hearing the presiding officer can recommend that the order be affirmed, modified, or vacated, or amended to require a recall. If there is a reasonable probability that death would occur if distribution of the device were to cease, the presiding officer may recommend to the agency at the conclusion of the hearing that the individual named in the order be permitted to distribute the device. The agency will base its final decision on the presiding officer's report. This process will ensure that individuals will have ample opportunity to advise the agency that they believe that a recall under consideration is ill conceived.

11. A comment stated that the rule leaves the following questions unanswered:

(a) What will customers do if they are in the midst of recall efforts and then they are informed that a recall has been modified or canceled altogether?

FDA believes that the comment is concerned with what customers should do when FDA has issued a cease distribution and notification order, the individual named in the order has complied with such order, a regulatory hearing has been held, and FDA has vacated the cease distribution and notification order. In this circumstance, the customers affected by the order may resume using the device as they did prior to the issuance of the cease distribution and notification order.

(b) Is it intended that manufacturers notify their customers twice—once about a cease distribution order and later about a recall order?

Yes. According to section 518(e)(1)(B) of the act, under a cease distribution and notification order, the individual named in the order must, among other things, notify health professionals and device user facilities of the order. If FDA subsequently amends the cease distribution and notification order to include a recall order, the individual named in the order must notify health professionals and device user facilities, as well as individuals subject to the risks associated with use of the device. (See section 518(e)(2)(B)(ii) of the act.)

12. Several comments recommended that all references to notifying or communicating with health professionals, device user facilities, and or individuals be replaced with references to notifying or communicating with consignees only.

FDA disagrees. The mandatory recall regulations are being established in accordance with the authority granted to FDA under section 518(e) of the act. Section 518(e)(1)(B) of the act requires the person named in a cease distribution and notification order to immediately notify health professionals and device user facilities of the order when FDA has determined that the standard for issuance of a cease distribution and notification order has been met. Under section 518(e)(2)(B)(ii) of the act, if the cease distribution and notification order is subsequently amended to include a recall order, the person named in the order must notify individuals subject to the risks associated with the use of the device, including, where appropriate, the patients themselves. Thus, under section 518(e) of the act (21 U.S.C. 360h(e)) FDA may not by regulation limit notification and communications to consignees only.

B. Specific Comments

1. Section 810.1

One comment stated that this section needs to clarify whether manufacturers ought to follow the regulation in the event of a voluntary recall. In such a case, will FDA impose these regulations in addition to voluntary efforts undertaken by manufacturers?

The answer is no, FDA will not routinely order a mandatory recall if a voluntary recall has been effective in addressing the problems. Under § 7.3(g), a firm may initiate a voluntary recall of a product that is in violation of the laws FDA administers and against which FDA would initiate legal action. FDA initiates a mandatory recall under section 518(e) of the act when FDA finds that there is a reasonable probability that a device would cause serious, adverse health consequences or death. Voluntary recalls therefore apply to violative devices that may also be subject to mandatory recall because they have a reasonable probability of causing serious, adverse health consequences or death. A firm may initiate a voluntary recall of a violative device without FDA intervention; however, if FDA determines that such a voluntary recall is not effective in remedying a violation and there remains a reasonable probability that the violative device would cause serious, adverse health consequences, FDA will invoke the medical device recall authority in addition to the voluntary efforts that the manufacturer has already undertaken.

2. Section 810.2(d)

Two comments stated that including all users within the definition of ''consignee'' is too broad. According to one comment, a manufacturer or distributor transfers the finished device to the consignee, and cannot control, record, or report user identity unless the user is also the consignee.

FDA disagrees. As stated in the preamble to the proposed rule, the definition of consignee was based on the definition of consignee found in § 7.3. FDA intended the definition of consignee found in § 7.3 to indicate that a recall may extend not only to customers to whom the firm directly shipped the product, but also to those commercial establishments that in turn received shipment of the product from the first customer. (See 43 FR 26202 at 26210, June 16, 1978.) With the exception of those devices that have been identified as tracked devices, the agency did not intend to imply that a recalling firm is expected or required to know to whom its products are ultimately sold. Nor does the agency intend to imply that the person named in the cease distribution and notification order is expected or required to know to whom its products are ultimately sold. Nevertheless, although the manufacturer or distributor may not be able to identify the user, the commercial establishment that received the device from the manufacturer or distributor and who in turn shipped the device to the user will be able to identify the user.

The definition of ''consignee'' intentionally includes the term ''used a device'' in the event that a cease distribution and notification order or mandatory recall extends to the user level as authorized under section 518(e)(2) of the act and §§ 810.13(b)(1) and 810.14(c)(1)(i)(A) of the regulations. Moreover, FDA is clarifying that the term ''consignee'' does include health professionals, but does not include lay individuals or patients, i.e., nonhealth professionals.

3. Section 810.2(e) and (k)

A comment requested that the word ''inspection'' be removed from the definitions of ''correction'' and ''removal'' because an inspection is not

an intervention making a change to the device as are all the other terms included in the definitions.

FDA disagrees. The term ''inspection'' is properly linked to the definitions of ''correction'' and ''removal.'' Although an ''inspection'' is not an intervention making a change to the device, it is a mechanism for ensuring that proper changes to a device have been completed in accordance with a cease distribution and notification or recall order. Furthermore, in § 7.3(h) of the voluntary recall regulations, FDA included the term ''inspection'' in the definition of ''correction'' to cover those situations in which a device may still be used because circumstances would prevent repair or removal of a device, e.g., an implanted device, but would nevertheless require positive action to ensure the device in use is being properly monitored by a physician. (See 43 FR 26202 at 26208, June 16, 1978.) Under the medical device recall regulations, an inspection is considered a correction under the same circumstances. Finally, FDA has amended the term ''correction'' to include ''destruction.''

4. Section 810.2(h)

Two comments noted that the proposed definition of ''reasonable probability'' was written in the future tense. As proposed, these comments contended, the definition would allow FDA to impose a mandatory recall on mere suspicion. Accordingly, these comments requested that the definition be written in the past tense.

FDA disagrees. The main purpose of a cease distribution and notification or recall order is to avoid a serious, adverse health consequence or death. Accordingly, the likelihood that such harm will result from the continued distribution and use of the device, and not only the actual occurrence of such a harm, is the appropriate definition. The agency therefore adopted the definition of the term ''reasonable probability'' that is found in the legislative history (S. Rept. 513, 101st Cong., 2d sess. 19 (1990)), which is written in the future tense. However, FDA does not interpret this to mean that the agency can act on ''mere suspicion.'' The agency needs a firm basis for issuing an order under part 810, and that basis must be communicated in writing to the firm.

5. Section 810.2(i)

(a) One comment stated that the definition of ''serious, adverse health consequences'' is vague. Because the term is the key element that determines whether it is appropriate to order a notification or recall, it is imperative that the definition be focused and clearly stated. In addition, this comment stated that in order to provide some consistency among regulatory programs, FDA should make this definition relate to the definition of ''serious injury'' in the medical device reporting regulations found in 21 CFR part 803.

FDA disagrees. The definition of ''serious, adverse health consequences'' is clearly stated and consistent with congressional use of the term in the legislative history. (See S. Rept. 513, 101st Cong., 2d sess. 19 (1990)). Moreover, this definition is a crucial concept, not only for recall authority, but also for two other SMDA provisions: Suspension of approval of a premarket approval application and postmarket surveillance. Therefore, this definition provides uniformity among other SMDA regulatory programs.

(b) Another comment requested that the term ''serious, adverse health consequence'' be redefined as an injury that is not treatable by standard medical techniques. The second sentence of the proposed definition, ''Injuries attributable to a device that are treatable and reversible by standard medical techniques, proximate in time to the injury, are not included within the term's definition,'' raises unnecessary questions as to the timeframe that must elapse for an injury to be deemed irreversible.

FDA disagrees. However, including the last sentence of the definition of ''serious, adverse health consequences'' is superfluous. The comparable sentence in the legislative history was intended only to further explain the type of injury excluded from the definition of serious, adverse health consequences. (See S. Rept. 513, 101st Cong., 2d sess. 19 (1990).) Accordingly, FDA has revised § 810.2(i) by deleting the second sentence.

6. Section 810.2(j)

(a) One comment recommended that the definition of ''recall'' be revised to comply with the current definition of ''voluntary recall,'' which restricts recalls to those actions relative to device defects ''against which the agency would initiate legal action.'' Another comment noted that the concept of a recall found in § 7.40 *et. seq.* is much broader than that embodied in this section. According to the comment, the proposed rule sets up a confusing inconsistency because it does not revise the existing regulation.

FDA disagrees with these comments. The voluntary recall provisions apply not only to medical devices but to all products subject to FDA jurisdiction (except electronic products subject only to subchapter C of the act). The medical device recall regulations apply only to medical devices that have a reasonable probability of causing serious, adverse health consequences or death. Thus, the applicability of the voluntary recall provisions is necessarily broader than, and the criteria for requesting a voluntary recall is purposefully different from, that of the medical device recall regulation. Moreover, a recall order issued under section 518(e) of the act will include a reference to the relevant statute and regulations which should preclude confusion between the two recall provisions.

(b) Another comment stated that it is confusing to include in this definition the connection to serious, adverse health consequences, or death. Because the term ''recall'' is used in other contexts, a reader unfamiliar with the context of the action in question would not be able to determine whether the recall was being conducted under this authority, under other sections of the act or regulations, or voluntarily by the manufacturer. Thus, the comment suggested revising the definition as follows: ''Recall means a firm's removal or correction of a marketed product.'' This comment also suggested that FDA consider modifying § 7.3(g) to read the same as the definition suggested above. Additionally, the comment recommended adding the following definition: ''Mandatory recall means a recall undertaken solely pursuant to an order from FDA which contains a finding that there is a reasonable probability that the product(s) involved in the recall would cause serious, adverse health consequences or death.'' In addition, it was recommended that FDA add a definition of the term ''voluntary recall'' to § 7.3 to read as follows: ''Voluntary recall means a recall of a marketed product undertaken voluntarily by a manufacturer when the manufacturer believes that FDA would consider the product to be in violation of the laws it administers.''

FDA disagrees. As stated above, the criteria for initiating a voluntary recall are different from the criteria for initiating a mandatory recall. FDA included both the criteria for, and the definition of, a recall in § 810.2(j) so that individuals would be able to determine the type of recall being initiated and to eliminate the need to add or amend any recall definitions. Moreover, a recall order issued under section 518(e) of the act will include a reference to the relevant statute and regulations, thereby eliminating any confusion.

7. Section 810.4

According to a comment, the magnitude of a mandatory recall or cease distribution and notification order is of such significance that FDA should not serve such orders by registered mail.

Overall, FDA agrees with this comment. In most cases, such orders will be served in person by a designated FDA employee. However, if FDA determines that personal service of the orders will delay section 518(e) actions, FDA will serve such orders by certified or registered mail or similar mail delivery service with a return receipt record reflecting receipt.

8. Section 810.10(c)

(a) According to one comment, it is not appropriate for FDA to specify beginning and completion dates for notifying health professionals and device user facilities. Depending on how those terms are interpreted, a number of factors could affect when an action can begin. As a result, this comment suggested deleting this provision.

FDA disagrees in part. Because cease distribution and notification actions are required to begin immediately upon issuance of such an order, FDA has determined that it is not appropriate for FDA to specify beginning dates for notifying health professionals and device user facilities. However, FDA has determined that, under § 810.10(c), FDA may include a model letter requiring that notification be completed within a specified timeframe. Thus, depending on the circumstances surrounding the issuance of such an order, FDA may find it essential that the cease distribution and notification order be completed within a specified timeframe.

(b) Another comment suggested that proposed § 810.10(c) be revised to include in the order a ''model'' letter that would only provide the key elements of information required to inform the customer of the situation.

As suggested by the comment, FDA has amended new § 810.10(c) by adding the following sentence: ''The model letter will include the key elements of information that the agency in its discretion has determined, based on the circumstances surrounding the issuance of each order, are necessary to inform health professionals and device user facilities about the order.''

9. Sections 810.10(c) and 810.13(b)(4)

A comment suggested that these sections be revised to indicate that the model letter is to ensure compliance with the terms and conditions of the cease distribution and notification order or recall order; it is not to provide suggested verbiage for the notification of consignees, and it is not binding upon medical device manufacturers.

FDA disagrees. The model letter will be binding on device manufacturers. Based on the circumstances of each case, FDA in its discretion will determine that the information contained in a model letter is necessary to notify health professionals and device user facilities of the cease distribution and notification or mandatory recall situation. If this information is not included in a manufacturer's letter, the manufacturer is not providing adequate information to health professionals and device user facilities, and, as a result, the person named in the order would not be in compliance with the cease distribution and notification order or mandatory recall order.

10. Section 810.10(d)

A comment stated that, under certain circumstances, a manufacturer may not be able to provide all of the information specified in proposed § 810.10(d). Thus, the comment recommended the following revision: ''FDA may * * * require the person named in the * * * order to submit any or all of the following information by a time specified in the order, to the extent it is available or readily ascertainable within the time specified by FDA.''

FDA disagrees. Under § 810.10(d), FDA has the discretion to require that the person named in the order submit any or all of the specified information. If, in exercising that discretion, FDA determines that any or all of the information listed in this section is necessary to monitor compliance with the cease distribution and notification order, or to determine whether additional action is necessary, the person named in the order must submit such information. If a particular manufacturer cannot locate certain required information because of an uncooperative consignee or other reasons, the manufacturer may contact FDA to find out whether there is information that it may submit in lieu of the required information. In addition, section 518(e) of the act specifically authorizes FDA to issue cease distribution and notification orders to appropriate persons, including manufacturers, importers, distributors, or retailers. FDA will therefore also consider issuing a cease distribution and notification order to a manufacturer, importer, distributor, or retailer who does not cooperate with a person to whom FDA has issued a cease distribution and notification order.

11. Section 810.10(d)(1) and (d)(2)

A comment noted that proposed § 810.10(d)(1) and (d)(2) seem to require the same information. Thus, it was suggested that these paragraphs be combined into one information request.

FDA agrees. However, instead of combining these two paragraphs, FDA has revised new § 810.10(d)(1) to read: ''The total number of units of the device produced and the timespan of the production.'' This change makes this paragraph correspond with § 7.46(a)(4).

12. Section 810.10(d)(3) and (d)(4)

It was requested that the term ''estimated'' be added to § 810.10(d)(3) and (d)(4) to reflect the fact that the numbers submitted to FDA can only be estimated by the company. This addition would be similar to the use of the term ''estimated'' in § 810.10(d)(2).

FDA agrees and has revised the sections accordingly.

13. Section 810.10(d)(5)

Section 810.10(d)(5) uses the term ''direct'' consignee. Section 810.2(d), which defines consignee, does not refer to a distinction between a direct consignee and a consignee. Accordingly, it was suggested that FDA either: (1) Add a definition for direct consignees or (2) modify the term consignee to include only direct consignees and delete the word direct from this section.

FDA has removed the term ''direct'' from this section. Thus, this section applies to all consignees as defined in § 810.2(d). As stated previously in section IV.B.2. of this document, FDA did not intend to imply that the person named in the cease distribution and notification order or recall order is expected or required to know to whom its products are ultimately sold. However, although the manufacturer or distributor may not be able to identify all consignees, the commercial establishment that received the device from the manufacturer or distributor and who in turn shipped the device to a subsequent consignee will be able to identify the subsequent consignee.

14. Section 810.10(d)(8)

A comment stated that it is unnecessary to require the times individuals were contacted under the cease distribution and notification order. Accordingly, the comment suggested striking the phrase ''and times'' from this section. Moreover, it was suggested that the phrase ''names of specific individuals contacted within user facilities'' be eliminated in its entirety.

FDA agrees that requiring the person named in the cease distribution and

notification order to document the ''times'' that specific individuals within device user facilities were contacted is unnecessary. Providing FDA with the dates of such contacts is sufficient. FDA has amended this section accordingly. FDA disagrees, however, that the phrase ''names of specific individuals contacted within user facilities'' should be eliminated. Requiring such information will ensure against allegations of failure to notify device user facilities. If a question concerning notification of a user facility arises, FDA can simply contact the person listed as the ''specific individual contacted within the user facility'' to determine if he/she received notification.

15. Section 810.10(e)

A comment stated that a definition of the term ''opportunity'' should be added because there is a very short time from issuance of the order to the hearing and because there is only one hearing.

FDA disagrees. The agency believes that § 810.11 as amended, which establishes the procedures to be followed in requesting a regulatory hearing, implicitly explains the term ''opportunity.''

16. Section 810.11(b)(2)

A comment noted that this section omits language set forth in the statute that indicates that FDA may vacate the cease distribution and notification order should the agency determine that inadequate grounds exist to support the actions required by the order. Thus, the comment would append the following language to § 810.11: ''§ 810.11(g)—If, after providing an opportunity for such a hearing, whether acted upon or not, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.''

FDA disagrees. Appending the recommended language is unnecessary because § 810.11(b)(1) already addresses this issue.

17. Section 810.11(c)

(a) According to § 810.11(c), §§ 16.60(h) and 10.19 apply to the regulatory hearings provided under the medical device recall authority. These sections permit the waiver, suspension, or modification of any otherwise applicable procedure in part 16. A comment requested that it be explicitly stated in the regulation that this flexibility does not permit the waiver of the opportunity for a regulatory hearing itself, since that right is guaranteed by section 518(e) of the act.

Another comment stated that the intent expressed in proposed § 810.11(c) seems to be beyond the scope of § 10.19, which states that a provision of part 16 may be waived, suspended, or modified only if ''no participant will be prejudiced.'' According to the comment, under part 810, it is difficult to see how a manufacturer would not be prejudiced by any action that reduces or eliminates its procedural and substantive rights.

FDA disagrees with these comments. Under § 810.11(c), a part 16 procedure may be waived, suspended, or modified in accordance with § 10.19. Under § 10.19, a part 16 procedure may be waived, suspended, or modified if a participant will not be prejudiced, the ends of justice will be served, and the action is in accordance with the law. Moreover, section 518(e)(1) of the act requires FDA to provide the person subject to a cease distribution and notification order with an opportunity for a regulatory hearing. Under 21 CFR 16.26, the Commissioner of Food and Drugs or the presiding officer may deny, in whole or in part, a request for a hearing if he or she determines that the material submitted in support of the request raises no genuine and substantial issue of fact. Therefore, no person subject to a cease distribution and notification order will be denied the opportunity for a regulatory hearing. If such person fails to raise a genuine and substantial issue of fact in requesting a hearing, however, he or she may be denied a hearing. In addition, once a regulatory hearing commences, the presiding officer may issue a summary decision on any issue if he or she determines that there is no genuine and substantial issue of fact respecting that issue.

Congress intended that FDA be able to give notice, hold an informal hearing, and render a decision on a recall in a single day, if ''circumstances require expedited action,'' i.e., when FDA believes that immediate action is necessary to protect the public health. (See H. Rept. 808, 101st Cong., 2d sess. 29 (1990).) (See also 61 FR 15186, April 5, 1996.) Although § 810.11 provides that recall hearings will not generally be conducted fewer than 5 days after notice is given by the cease distribution and notification order, the person named in a cease distribution and notification order has no procedural right under the statute to 5 days notice of the hearing. Section 810.11(c) therefore properly reserves discretion for the Commissioner or presiding officer to suspend, waive, or modify the procedural provisions of part 16, including those pertaining to the timing of the hearing.

(b) Another comment stated that FDA seems to be overstating the scope of its authority under §§ 16.60(h) and 10.19. As proposed, § 810.11(c) stated that ''the agency may waive, suspend, or modify,'' whereas § 16.60(h) states that only the ''Commissioner or the presiding officer has the power to suspend, modify, or waive any provision'' in part 16. In addition, as proposed, § 810.11(c) stated that any ''procedure'' may be waived, suspended, or modified, while § 16.60(h) refers only to ''any provision of this part.''

FDA agrees and has amended § 810.11(c) to conform to §§ 16.60(h) and 10.19.

18. Section 810.11(e)

A comment maintained that due process concerns dictate that the 10-day period before a hearing will be held beginning on the date of receipt, rather than the date of issuance of the order.

FDA disagrees. Given the exigent circumstances surrounding the issuance of cease distribution and notification orders, it is appropriate that the holding of a regulatory hearing be calculated based on the date of issuance of such orders. Moreover, section 518(e)(1) of the act requires that regulatory hearings be held no later that 10 days after issuance of such orders. However, as set forth in § 810.3, the day of issuance will not be included in the 10-day time period.

19. Sections 810.13, 810.14, and 810.15

According to one comment, proposed §§ 810.13, 810.14, and 810.15 should be revised to emphasize that the provisions are intended as guidance and are not mandatory. Orders should be tailored to specific circumstances and should be as flexible as possible both in their formulation by FDA and in their implementation by the respondent.

FDA believes that these sections are already tailored to address the specific circumstances surrounding the issuance of each order. Although some aspects of a recall order, a cease distribution and notification or mandatory recall strategy, and communications concerning a cease distribution and notification or mandatory recall order are mandatory, some aspects vary depending on the order. Instead of having specific and rigid instructions to cover all orders, FDA believes these sections include only the basic elements of each. For instance, according to § 810.13(b), FDA has discretion in determining what is appropriate for a recall order based on the individual circumstances. Moreover, § 810.14(a) states that ''[t]he person named in a cease distribution and notification order * * * or a mandatory recall order * * * shall develop a strategy * * * that is

appropriate for the individual circumstances * * *.'' Finally, § 810.15(a) states that ''[t]he person named in a cease distribution and notification order * * * or a mandatory recall order * * * is responsible for promptly notifying each health professional, device user facility, consignee, or individual, as appropriate, of the order.'' Thus, a recall order, a cease distribution and notification or mandatory recall strategy, and the communications concerning the cease distribution and notification order or mandatory recall order will vary depending on the circumstances surrounding the issuance of each order.

20. Section 810.13(b)(2)

Two comments stated that it is virtually impossible for a manufacturer or FDA to predict with any degree of accuracy when a recall will be completed. Under the current voluntary recall provision, a manufacturer may request termination of a recall by demonstrating that the recall has been effective (§ 7.55). Thus, the comments suggested that proposed § 810.13(b)(2) be revised to read that FDA may specify a timetable in accordance with which the recall is to occur and to reference the recall termination procedures from § 810.17, instead of specifying a timetable in which the recall is to be completed.

FDA disagrees. Section 810.13(b) states: ''In a mandatory recall order, FDA may * * * (2) Specify a timetable in accordance with which the recall is to begin and be completed.'' This section is in accordance with the recall authority legislative history, which states: ''The bill does not have specific timetables under which recalls must occur * * *; the Committee believes that it is more appropriate to allow the Secretary, dependent on the circumstances of each case, to establish the time-frames for completion of the recall.'' (See S. Rept. 513, 101st Cong., 2d sess. 20 (1990)). FDA believes that this section, as drafted, vests with the agency the discretion to establish recall completion dates that depend on the facts surrounding the issuance of each order, in conformance with legislative intent. It is therefore unnecessary for this section to reference the termination procedures set out in § 810.17.

21. Section 810.13(c)(2)

A comment suggested that all references to a competitor's product be eliminated from this subsection. The decision to replace a defective device with a competitor's product poses conflict of interest concerns for both the agency and manufacturer.

In response to this comment, FDA has deleted any reference to ''competitor's product'' from § 810.13(c)(2). FDA will not explicitly reference a competitor's product in mandatory recall orders. However, the agency may consider availability of alternate products, including those produced by competitors, when determining whether to amend a cease distribution and notification order to require a recall. Clearly, the availability of alternate products is an important and relevant factor that FDA may consider in comparing the risk of recalling the device with the risk of not recalling it.

22. Section 810.13(e)

(a) A comment noted that if FDA can issue a mandatory recall, after initially deciding not to issue one, based on noncompliance with the cease distribution and notification order, then the findings of the regulatory hearing become moot. Another comment stated that ''noncompliance with the cease distribution and notification order'' should be determined on a case-by-case basis. Another comment requested that this section be deleted because, according to this comment, it is clear that Congress did not intend for FDA to have the unilateral authority to issue a mandatory recall order without notice and participation of the affected party through appropriate due process protections such as a regulatory hearing.

As stated in section IV.A. of this document, FDA has omitted § 810.13(e) from the final rule in response to comments.

23. Sections 810.14(a)(5) and 810.17(b)(1)

According to two comments, proposed § 810.14(a)(5) should state clearly that the information sought only concerns the effectiveness of the level of the manufacturer's notification, rather than the intrusion into the practice of medicine by the manufacturer to determine the extent to which the health professionals and device user facilities are complying with instructions. Thus, these comments suggested revising this section to read as follows: ''The extent to which notification and instruction of health professionals and user facilities has been achieved.''

Proposed § 810.14(a)(5) required that the firm consider information about the success of efforts to inform users to cease use of the device, and FDA has determined that this information will not generally be available to the firm by the time it must submit its strategy to FDA. Therefore, FDA has deleted this section from the general provision part of the final regulation.

Two comments stated that § 810.17(b)(1) needs to omit any suggestion that the manufacturer has the legal requirement to ensure that all health professionals, device user facilities, consignees, and applicable individuals have complied with instructions to cease the use of the device because manufacturers are not required to monitor compliance with the order.

FDA agrees in part with the comment. In proposing § 810.17(b)(1), FDA did not intend to suggest that the manufacturer is legally required to ensure that all health professionals, device user facilities, consignees, and, where appropriate, individuals have complied with the cease distribution and notification order. FDA did intend, however, to require the manufacturer to verify that health professionals, device user facilities, consignees, and, where appropriate, individuals have been notified of the cease distribution and notification order and have been instructed to take appropriate action, and FDA has amended § 810.17(b)(1) to clarify it. FDA considers such verification the responsibility of the person named in the order. Requiring such verification under § 810.17(b)(1) assures the public that FDA has determined that all reasonable efforts have been made to implement the cease distribution and notification order.

24. Section 810.14(a)(7) (renumbered § 810.14(b)(2) in the final regulation)

(a) According to a comment, this section grants FDA undue discretion to review the elements of a proposed recall strategy. This comment stated that FDA's authority to review and modify a manufacturer's recall strategy must be limited to the power to require modifications that ensure that the recall is effective in addressing serious, adverse health consequences or death.

FDA believes that § 810.14 provides the agency with the discretion necessary to effect the statutory purpose. Each cease distribution and notification order modified under § 810.11(e) or § 810.12(c) or recall order requires devising a specific course of action to implement the order. In developing a strategy for either a cease distribution and notification order modified under § 810.11(e) or § 810.12(c) or a recall order, the person named in the order must take into account the factors listed in § 810.14(a) and meet the requirements listed in § 810.14(c) of the final regulation. FDA will review the adequacy of the strategy proposed by the person named in the order. (See

§ 810.14(b)(2).) If the person named in the order has appropriately considered all the factors listed in § 810.14(a) and included the requirements listed in § 810.14(c), FDA will find the strategy acceptable. When the agency in its discretion finds that the person named in the order has not given appropriate consideration to relevant factors (§ 810.14(a)) and requirements (§ 810.14(c)), FDA will mandate changes in the strategy. FDA's authority to review and modify a manufacturer's strategy therefore allows it to require modifications that ensure that the cease distribution and notification strategy or mandatory recall strategy will be effective in addressing serious, adverse health consequences or death.

(b) The comment also stated that, to the extent that § 810.14(b)(2) allows FDA to impose a strategy on the manufacturer, it is unreasonable. At a minimum, FDA should consult with the individuals responsible for the strategy prior to making any changes to the strategy or should provide the manufacturer with an opportunity to have a hearing on the reasonableness and appropriateness of a proposed strategy. Moreover, it is unreasonable for FDA to require the manufacturer to begin to implement the submitted strategy before FDA has reviewed it.

FDA agrees in part with the comment and has amended proposed § 810.14(b)(2) accordingly. Section 810.14(b)(2) now states that the agency will complete review of a proposed strategy for a cease distribution and notification order modified under § 810.11(e) or § 810.12(c) within 7 days of receipt. The person named in the order shall act in accordance with a strategy only after FDA has determined that the strategy is appropriate.

FDA disagrees, however, that the agency should provide the manufacturer with an opportunity to have a hearing on the reasonableness and appropriateness of a proposed strategy. An additional hearing to address the appropriateness of the firm's proposed strategy cannot be granted because of the exigent circumstances surrounding the issuance of such orders. However, under §§ 810.11(b)(1) and 810.12(b), the regulatory hearing and written request for review may address the actions required by the cease distribution and notification order, including an appropriate cease distribution and notification strategy if the cease distribution and notification order is modified. Furthermore, under §§ 810.11(b)(2) and 810.12(b), the regulatory hearing and written request for review may also address whether FDA should amend the order to require a recall, including an appropriate recall strategy if FDA should determine that a recall is warranted.

(c) According to the comment, proposed § 810.14(a)(6) and (a)(7) are not appropriate factors to be considered in developing a cease distribution and notification or recall strategy. Thus, the comment suggested that proposed § 810.14(a)(6) and (a)(7) be removed from the list of factors to be considered and be included in another paragraph, i.e., paragraph (b).

The agency agrees. FDA has therefore renumbered paragraph (a)(6) and (a)(7) as (b)(1) and (b)(2), respectively, under a new paragraph (b) heading ''Submission and review.'' Accordingly, current paragraph (b) has been renumbered as paragraph (c).

25. Section 810.14(b)(3) (renumbered § 810.14(c)(3))

One comment stated that a manufacturer's responsibility to conduct effectiveness checks should be limited to direct consignees. Another comment recommended that the word ''all'' be deleted from the first sentence because it would be virtually impossible for a recall strategy to verify that ''all'' of the target audience was actually reached. Instead, it was suggested that the regulation require that an appropriate level of effectiveness checks be established in advance of the strategy.

FDA disagrees that a manufacturer's responsibility to conduct effectiveness checks should be limited to direct consignees. The purpose of effectiveness checks is to verify that all known, affected consignees have received notification about a particular recall order. Thus, if a recall extends to the user level, as authorized by § 810.13(b)(1), it is imperative that all known affected consignees, direct and indirect, receive notification of the order. For these same reasons, FDA disagrees with deleting the word ''all'' from the first sentence.

FDA recognizes, however, that in some instances the person named in the recall order may not be able to check the effectiveness of its recall; for example, manufacturers, importers, distributors, or retailers may not cooperate. In such cases, FDA will directly assist in the effectiveness check activity and, where necessary, seek assistance from cooperating State and local agencies. In addition, as stated previously, section 518(e) of the act specifically authorizes FDA to issue cease distribution and notification orders to appropriate persons, including manufacturers, importers, distributors, or retailers. FDA will therefore also consider issuing a cease distribution and notification order to a manufacturer, importer, distributor, or retailer who does not cooperate with a person to whom FDA has issued a cease distribution and notification order.

26. Section 810.15(b)

According to a comment, limiting the communications to written notices is unduly restrictive. Therefore, this comment suggested revising this section to specify that telephonic or other electronic means of communication may be used when appropriate.

FDA disagrees. Requiring communication by verified written notice ensures that the person named in the order will have written proof of notification if a question of noncompliance is raised. However, the person named in an order may utilize telephonic or electronic means in addition to verified written notices.

27. Section 810.15(e)

According to one comment, under section 518(e) of the act only those persons who have been provided with notice and an opportunity for a hearing on a cease distribution and notification or mandatory recall order are legally bound by such an order. Thus, this section should be modified to state that recipients of a communication concerning a cease distribution and notification or a mandatory recall order are instructed to take appropriate actions, rather than create the impression that they are legally obligated to do so.

FDA has used the term ''should'' instead of ''shall'' throughout this section in order to encourage recipients of such communications who are not otherwise legally obligated by a cease distribution and notification or mandatory recall order to take appropriate actions under the order. Furthermore, FDA considers such orders strong advisories for health professionals. FDA anticipates that health professionals will exercise their best clinical judgment in deciding whether ceasing use of the medical device is in the best interest of their patients based on the information available to them as well as the availability of alternate devices.

28. Section 810.16(b)(1) through (b)(4)

One comment finds that the references to ''individuals'' contacted about the order in these sections is confusing given the fact that section 518(e) of the act and § 810.13(c)(1) provide that no mandatory recall order will be issued to individuals. Thus, the comment recommended deleting the term ''individuals'' from this section.

FDA disagrees. Section 518(e)(2)(B)(i)(I) of the act and § 810.13(c)(1) provide that a mandatory recall order will not require recall of a device from an individual. However, section 518(e)(2)(B)(ii) of the act and § 810.13(d) state that a mandatory recall order will provide notice to individuals subject to the risks associated with use of the recalled device. Therefore, the reference to ''individuals'' in these sections is appropriate because it applies to notification of risk, not to product recall.

29. Section 810.16(b)(6)

A comment suggested that the timeframes be arrived at as the result of a collaborative dialogue between the agency and the person named in the cease distribution and notification or mandatory recall order, rather than be imposed by FDA. Another comment stated that because it is not possible to predict the completion of a recall, the section should be revised to read: ''Estimated time-frame for completion of the requirements of the cease distribution and notification order.''

FDA does not believe that collaborative dialogue between FDA and industry is foreclosed by § 810.16(b)(6), which merely requires that status reports on cease distribution and notification orders and recall orders, which the person subject to the order submits to FDA, contain estimated timeframes for completion of the requirements of cease distribution and notification orders, if warranted, and mandatory recall orders as required under section 518(e)(2)(A) of the act. (See §§ 810.10(c) and 810.13(b)(2).) Moreover, the hearing under § 810.11 will provide an opportunity to review actions required by both orders, including the timeframes for completion of those actions. FDA does expect all recall-related activity to be completed and final status reports submitted for termination within 6 months of issuance of recall orders. FDA therefore disagrees with the comment that suggests revision of this section to eliminate reference to mandatory recall orders.

30. Section 810.18

A comment stated that FDA should be required to publish any mandatory recall in the FDA Enforcement Report within 30 days of the recall order or cease distribution and notification order. If the recall is listed in the FDA Enforcement Report within 30 days of the recall notification letter to consignees, then the relationship between the two notifications will be apparent to all interested parties.

Although FDA agrees it is desirable to list mandatory recall information in the weekly Enforcement Report as soon as possible, there are a number of factors, some of which the agency may not control, that determine when the agency has sufficient information to list a recall on the weekly FDA Enforcement Report. These factors will vary from one case to another. Because of this variation, it is not always possible to predict and schedule the exact time the agency will be able to list publicly a particular recall. Moreover, in limited circumstances, FDA may intentionally delay public notification of recalls of certain devices when the agency determines that public notification may cause unnecessary harm and anxiety to patients and that initial consultation between patients and their doctors is essential.

V. Summary of Changes from the Proposed Rule

Although the agency maintained the basic framework of the proposed rule, FDA modified the proposed rule to address concerns raised in the comments.

In response to concerns raised in the comments, FDA made the following changes:

(1) If, after providing the appropriate person with an opportunity to consult with the agency, FDA finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, the agency may issue a cease distribution and notification order (§ 810.10(a)).

(2) FDA will be given 15 working days to complete its deliberative process following the completion of a regulatory hearing (§ 810.11(e)) or receipt of a written request for review of a cease distribution and notification order (§ 810.12(c)). Accordingly, under § 810.13(a), FDA will amend a cease distribution and notification order to include a mandatory recall within 15 working days of issuance of the cease distribution and notification order if a regulatory hearing or agency review of the order is not requested, or within 15 working days of denying a request for a hearing, or within 15 working days after completing a regulatory hearing, or within 15 working days of receipt of a written request for review of a cease distribution and notification order.

(3) Amended § 810.12(a) provides that the individual submitting a written request for review of a cease distribution and notification order must submit such a request within the timeframe specified in the order which will be, in most cases, within 10 working days of issuance of such an order, but not generally less than 3 working days after receipt of the cease distribution and notification order. This amendment is consistent with: (a) Section 810.11(a) which requires that a request for a regulatory hearing be submitted in writing within the timeframe specified by FDA (which under § 16.22(b), will not ordinarily be less than 3 working days after receipt of the cease distribution and notification order); and (b) § 810.11(e) which requires a regulatory hearing to be held within 10 working days of issuance of a cease distribution and notification order.

(4) Under § 810.14(b)(2), the agency will review and amend, reject, or accept a proposed strategy for a cease distribution and notification order modified under § 810.11(e) or § 810.12(c) or a mandatory recall within 7 working days of receipt of such a strategy.

(5) According to § 810.17(c), FDA will respond to a written request for termination of a cease distribution and notification or recall order within 30 working days of its receipt.

(6) FDA clarified that the opportunity for a regulatory hearing provided for in § 810.11 will be subject to the provisions set out in part 16 by making the following amendments:

(a) The agency has changed § 810.11(a) to provide that the person offered an opportunity for a hearing has the amount of time specified in the cease distribution and notification order to request a hearing. In accordance with § 16.22(b), FDA will ordinarily not require that such request be made in fewer than 3 working days after receipt of the order.

(b) Under § 16.24(e), the agency has changed § 810.11(e) to provide that a hearing will ordinarily not be held fewer than 2 working days after receipt of the request for hearing. Thus, the person named in the cease distribution and notification order will generally have at least 5 working days following receipt of the order before a regulatory hearing is held, unless FDA and the person named in the order agree to a later date or the presiding officer determines otherwise. Moreover, in accordance with § 16.60(h), the Commissioner of Food and Drugs or the presiding officer has the power under § 10.19 to suspend, modify, or waive any provision of part 16.

(c) The agency has referenced § 16.26(a) and (b) in § 810.11(a) and (c) to clarify that a request for a regulatory hearing may be denied in whole or in part and that a summary decision on an issue may be issued once a regulatory hearing commences if there is no

genuine and substantial issue of fact raised in the request for a hearing or about an issue once a hearing commences. The agency has amended § 810.11(b) and (c) to clarify that they apply if the agency grants a request for a regulatory hearing.

(7) FDA revised the definition of serious, adverse health consequences in § 810.2(i) by deleting the second sentence in the proposed definition.

(8) FDA clarified the definition of consignee in § 810.2(d).

(9) In § 810.3, FDA changed the computation of time method to working days.

(10) FDA revised § 810.4 so that a cease distribution and notification order or recall order will be served in person by a designated FDA employee in most cases.

(11) FDA deleted proposed § 810.10(d)(9) from the final regulation and has redesignated proposed § 810.10(d)(10) as § 810.10(d)(9) in the final regulation.

(12) FDA amended § 810.11(a), (c), and (e) to conform to §§ 16.60(h) and 10.19.

(13) FDA deleted § 810.14(a)(5) from the final regulation because the information sought under this section will not generally be available to the firm by the time it must submit its strategy to FDA.

(14) FDA renumbered proposed § 810.14(a)(6) and (a)(7) as § 810.14(b)(1) and (b)(2), respectively, under a new paragraph (b) heading entitled ''Submission and review'' in the final regulation. As a result of this modification, FDA has renumbered proposed § 810.14(b) as § 810.14(c) under the same paragraph (c) heading ''Elements of the strategy.''

(15) FDA amended various paragraphs of § 810.10. First, FDA revised § 810.10(d)(1) to read: ''The total number of units of the device produced and the timespan of the production.'' Second, FDA added the term ''estimated'' to § 810.10(d)(3) and (d)(4).

(16) FDA removed the term ''direct'' from § 810.10(d)(5).

(17) FDA omitted from the final rule § 810.13(e) which provided FDA with the authority to initially determine that a cease distribution and notification order need not be amended to require a mandatory recall, but subsequently amend the order to require a recall of the device if the agency made specific findings. Under the final rule, if FDA initially determines that a device does not pose a reasonable probability of causing serious, adverse health consequences or death, the agency will vacate the order. If, however, FDA subsequently finds that the device, which was subject to the original cease distribution and notification order which was vacated, poses a reasonable probability of causing serious, adverse health consequences or death, the agency will issue a new cease distribution and notification order. If a new cease distribution and notification order is issued, the person subject to the order will be provided with the opportunity for a regulatory hearing as required by section 518(e)(1) of the act and § 810.11 of the regulation or with the opportunity to submit a written request for review of a cease distribution and notification order under § 810.12 of the regulation.

VI. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, the Regulatory Flexibility Act (Pub. L. 96–354), as amended by Subtitle D of the Small Business Regulatory Fairness Act of 1996 (Pub. L. 104–121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). 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). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. A comment stated that this rule will have a significant impact on small entities. Thus, the comment stated that further analysis under both Executive Order 12866 and the Regulatory Flexibility Act is warranted.

FDA disagrees with this comment. FDA has examined the rule under the Regulatory Flexibility Act and Executive Order 12866. The rule merely establishes the procedures by which FDA will implement its authority for the cessation of distribution and use and recall of a device. FDA cannot predict the cost of any action that would be ordered under this rule. However, FDA believes that it has provided sufficient flexibility in the rule so as to minimize the burden on those required to take action consistent with the determination that the device presents a risk of serious adverse health consequences or death. For example, § 810.10(a) provides entities with an opportunity to consult with FDA before FDA issues a cease distribution and notification order. In addition, § 810.11 provides an opportunity for a regulatory hearing and § 810.12 provides an opportunity for written review of an order. Lastly, § 810.14 provides that the person required to carry out the recall order may develop a strategy for carrying out a recall subject to FDA review. These provisions will provide entities with the opportunity to advise the agency about cost effective means to protect the public health.

The agency believes that only a small number of firms will be affected by this rule. Under this rule, the agency would invoke section 518(e) of the act in those instances that match very closely the definition of class I recall, where there is a strong likelihood that the use of or exposure to a device would cause serious, adverse health consequences or death (compare § 7.3(m)(1) and section 518(e)). The greatest number of class I recalls in 1 year to date has been 36, and the average over the last 5 fiscal years has been 19 per year. FDA expects that almost all of the recalls will continue to be carried out under the voluntary recall, part 7 procedures. The agency expects that at most one or two recalls per year would be ordered that would not have occurred without this regulation. Thus, the agency believes that this new authority will not be used frequently. The agency is unable to estimate the cost of this rule because it is unable to predict the nature or size of recalls that may be ordered. FDA believes, however, that the costs will not be excessive for the recall of a device that presents a risk of serious adverse health consequences or death, given the limited number of recalls that will be ordered and the flexibility that is allowed to implement them. For these reasons, the Commissioner certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required. In addition, this rule will not impose expenditures of $100 million or more on either State,

local, and tribal governments in aggregate or the private sector, and therefore a written statement under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

VIII. Congressional Review

This rule is not a major rule under the congressional review provisions of Subtitle E of the Small Business Regulatory Fairness Act of 1996 (Pub. L. 104–121).

IX. Paperwork Reduction Act of 1995

This final rule contains information collections which are subject to review by OMB under the Paperwork Reduction Act of 1995 (Pub. L. 104–13). The title, description, and respondent description of the information collections and an estimate of the annual reporting burden are shown below. Included in the estimate is the time for searching existing data sources, gathering and maintaining data needed, and completing and reviewing the collection of information.

Title: Reporting requirements for individuals named in cease distribution and notification orders and mandatory recall orders under the SMDA.

Description: This regulation establishes the procedures for implementing the medical device recall authority provided in the SMDA. The purpose of this regulation is to protect the public health by permitting FDA to promptly cease distribution of and recall dangerous devices from the market.

Description of Respondents: Businesses or other for profit organizations.

Although the June 14, 1994, proposed rule provided a 90-day comment period, and this final rule is based on the comments received, the proposed rule has not been previously available to OMB for review. Therefore, as required by section 3507(d) of the Paperwork Reduction Act of 1995, FDA will submit a copy of this final rule to OMB for review and approval of these information collection requirements. Organizations and individuals may submit comments on the information collection requirements by January 21, 1997. FDA particularly invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology. Comments should be directed to the Dockets Management Branch (address above).

At the close of the 60-day comment period, FDA will review the comments received, make revisions as necessary to the information collection requirements, and submit the requirements to OMB for review and approval. Additional time will be allotted for public comment to OMB on the requirements and OMB review. Prior to the effective date of this final rule, FDA will publish a notice in the Federal Register of OMB's decision to approve, modify, or disapprove the information collection requirements. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
810.10(d)	2	1	2	8	16
810.11(a)	1	1	1	8	8
810.12(b)	1	1	1	8	8
810.14	2	1	2	16	32
810.15	2	1	2	16	32
810.16	2	12	24	40	960
810.17	2	1	2	8	16
Total					1,072

There are no capital costs or operating and maintenance costs associated with this collection.

List of Subjects in 21 CFR Part 810

Administrative practice and procedure, Cease distribution and notification orders, Mandatory recall orders, Medical devices, Recordkeeping and reporting requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, new part 810 is added to read as follows:

PART 810—MEDICAL DEVICE RECALL AUTHORITY

Subpart A—General Provisions

Sec.

Subpart B—Mandatory Medical Device Recall Procedures

Authority: Secs. 201, 301, 302, 303, 304, 501, 502, 518, 701, 704, 705 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 332, 333, 334, 351, 352, 360h, 371, 374, 375).

Subpart A—General Provisions

§ 810.1 Scope.

Part 810 describes the procedures that the Food and Drug Administration will follow in exercising its medical device recall authority under section 518(e) of the Federal Food, Drug, and Cosmetic Act.

§ 810.2 Definitions.

As used in this part:

(a) *Act* means the Federal Food, Drug, and Cosmetic Act.

(b) *Agency* or *FDA* means the Food and Drug Administration.

(c) *Cease distribution and notification strategy* or *mandatory recall strategy* means a planned, specific course of action to be taken by the person named in a cease distribution and notification order or in a mandatory recall order, which addresses the extent of the notification or recall, the need for public warnings, and the extent of effectiveness checks to be conducted.

(d) *Consignee* means any person or firm that has received, purchased, or used a device that is subject to a cease distribution and notification order or a mandatory recall order. Consignee does not mean lay individuals or patients, i.e., nonhealth professionals.

(e) *Correction* means repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a device, without its physical removal from its point of use to some other location.

(f) *Device user facility* means a hospital, ambulatory surgical facility, nursing home, or outpatient treatment or diagnostic facility that is not a physician's office.

(g) *Health professionals* means practitioners, including physicians, nurses, pharmacists, dentists, respiratory therapists, physical therapists, technologists, or any other practitioners or allied health professionals that have a role in using a device for human use.

(h) *Reasonable probability* means that it is more likely than not that an event will occur.

(i) *Serious, adverse health consequence* means any significant adverse experience, including those that may be either life-threatening or involve permanent or long-term injuries, but excluding injuries that are nonlife-threatening and that are temporary and reasonably reversible.

(j) *Recall* means the correction or removal of a device for human use where FDA finds that there is a reasonable probability that the device would cause serious, adverse health consequences or death.

(k) *Removal* means the physical removal of a device from its point of use to some other location for repair, modification, adjustment, relabeling, destruction, or inspection.

§ 810.3 Computation of time.

In computing any period of time prescribed or allowed by this part, the day of the act or event from which the designated period of time begins to run shall not be included. The computation of time is based only on working days.

§ 810.4 Service of orders.

Orders issued under this part will be served in person by a designated employee of FDA, or by certified or registered mail or similar mail delivery service with a return receipt record reflecting receipt, to the named person or designated agent at the named person's or designated agent's last known address in FDA's records.

Subpart B—Mandatory Medical Device Recall Procedures

§ 810.10 Cease distribution and notification order.

(a) If, after providing the appropriate person with an opportunity to consult with the agency, FDA finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, the agency may issue a cease distribution and notification order requiring the person named in the order to immediately:

(1) Cease distribution of the device;

(2) Notify health professionals and device user facilities of the order; and

(3) Instruct these professionals and device user facilities to cease use of the device.

(b) FDA will include the following information in the order:

(1) The requirements of the order relating to cessation of distribution and notification of health professionals and device user facilities;

(2) Pertinent descriptive information to enable accurate and immediate identification of the device subject to the order, including, where known:

(i) The brand name of the device;

(ii) The common name, classification name, or usual name of the device;

(iii) The model, catalog, or product code numbers of the device; and

(iv) The manufacturing lot numbers or serial numbers of the device or other identification numbers; and

(3) A statement of the grounds for FDA's finding that there is a reasonable probability that the device would cause serious, adverse health consequences or death.

(c) FDA may also include in the order a model letter for notifying health professionals and device user facilities of the order and a requirement that notification of health professionals and device user facilities be completed within a specified timeframe. The model letter will include the key elements of information that the agency in its discretion has determined, based on the circumstances surrounding the issuance of each order, are necessary to inform health professionals and device user facilities about the order.

(d) FDA may also require that the person named in the cease distribution and notification order submit any or all of the following information to the agency by a time specified in the order:

(1) The total number of units of the device produced and the timespan of the production;

(2) The total number of units of the device estimated to be in distribution channels;

(3) The total number of units of the device estimated to be distributed to health professionals and device user facilities;

(4) The total number of units of the device estimated to be in the hands of home users;

(5) Distribution information, including the names and addresses of all consignees;

(6) A copy of any written communication used by the person named in the order to notify health professionals and device user facilities;

(7) A proposed strategy for complying with the cease distribution and notification order;

(8) Progress reports to be made at specified intervals, showing the names and addresses of health professionals and device user facilities that have been notified, names of specific individuals contacted within device user facilities, and the dates of such contacts; and

(9) The name, address, and telephone number of the person who should be contacted concerning implementation of the order.

(e) FDA will provide the person named in a cease distribution and notification order with an opportunity for a regulatory hearing on the actions required by the cease distribution and notification order and on whether the order should be modified, or vacated, or amended to require a mandatory recall of the device.

(f) FDA will also provide the person named in the cease distribution and notification order with an opportunity, in lieu of a regulatory hearing, to submit a written request to FDA asking that the order be modified, or vacated, or amended.

(g) FDA will include in the cease distribution and notification order the name, address, and telephone number of an agency employee to whom any request for a regulatory hearing or agency review is to be addressed.

§ 810.11 Regulatory hearing.

(a) Any request for a regulatory hearing shall be submitted in writing to the agency employee identified in the

order within the timeframe specified by FDA. Under § 16.22(b) of this chapter, this timeframe ordinarily will not be fewer than 3 working days after receipt of the cease distribution and notification order. However, as provided in § 16.60(h) of this chapter, the Commissioner of Food and Drugs or presiding officer may waive, suspend, or modify any provision of part 16 under § 10.19 of this chapter, including those pertaining to the timing of the hearing. As provided in § 16.26(a), the Commissioner or presiding officer may deny a request for a hearing, in whole or in part, if he or she determines that no genuine and substantial issue of fact is raised by the material submitted in the request.

(b) If a request for a regulatory hearing is granted, the regulatory hearing shall be limited to:

(1) Reviewing the actions required by the cease distribution and notification order, determining if FDA should affirm, modify, or vacate the order, and addressing an appropriate cease distribution and notification strategy; and

(2) Determining whether FDA should amend the cease distribution and notification order to require a recall of the device that was the subject of the order. The hearing may also address the actions that might be required by a recall order, including an appropriate recall strategy, if FDA later orders a recall.

(c) If a request by the person named in a cease distribution and notification order for a regulatory hearing is granted, the regulatory hearing will be conducted in accordance with the procedures set out in section 201(x) of the act (21 U.S.C. 321(x)) and part 16 of this chapter, except that the order issued under § 810.10, rather than a notice under § 16.22(a) of this chapter, provides the notice of opportunity for a hearing and is part of the administrative record of the regulatory hearing under § 16.80(a) of this chapter. As provided in § 16.60(h) of this chapter, the Commissioner of Food and Drugs or presiding officer may waive, suspend, or modify any provision of part 16 under § 10.19 of this chapter. As provided in § 16.26(b), after the hearing commences, the presiding officer may issue a summary decision on any issue if the presiding officer determines that there is no genuine and substantial issue of fact respecting that issue.

(d) If the person named in the cease distribution and notification order does not request a regulatory hearing within the timeframe specified by FDA in the cease distribution and notification order, that person will be deemed to have waived his or her right to request a hearing.

(e) The presiding officer will ordinarily hold any regulatory hearing requested under paragraph (a) of this section no fewer than 2 working days after receipt of the request for a hearing, under § 16.24(e) of this chapter, and no later than 10 working days after the date of issuance of the cease distribution and notification order. However, FDA and the person named in the order may agree to a later date or the presiding officer may determine that the hearing should be held in fewer than 2 days. Moreover, as provided for in § 16.60(h) of this chapter, the Commissioner of Food and Drugs or presiding officer may waive, suspend, or modify any provision of part 16 under § 10.19 of this chapter, including those pertaining to the timing of the hearing. After the presiding officer prepares a written report of the hearing and the agency issues a final decision based on the report, the presiding officer shall provide the requestor written notification of the final decision to affirm, modify, or vacate the order or to amend the order to require a recall of the device within 15 working days of conducting a regulatory hearing.

§ 810.12 Written request for review of cease distribution and notification order.

(a) In lieu of requesting a regulatory hearing under § 810.11, the person named in a cease distribution and notification order may submit a written request to FDA asking that the order be modified or vacated. Such person shall address the written request to the agency employee identified in the order and shall submit the request within the timeframe specified in the order, unless FDA and the person named in the order agree to a later date.

(b) A written request for review of a cease distribution and notification order shall identify each ground upon which the requestor relies in asking that the order be modified or vacated, as well as addressing an appropriate cease distribution and notification strategy, and shall address whether the order should be amended to require a recall of the device that was the subject of the order and the actions required by such a recall order, including an appropriate recall strategy.

(c) The agency official who issued the cease distribution and notification order shall provide the requestor written notification of the agency's decision to affirm, modify, or vacate the order or amend the order to require a recall of the device within 15 working days of receipt of the written request. The agency official shall include in this written notification:

(1) A statement of the grounds for the decision to affirm, modify, vacate, or amend the order; and

(2) The requirements of any modified or amended order.

§ 810.13 Mandatory recall order.

(a) If the person named in a cease distribution and notification order does not request a regulatory hearing or submit a request for agency review of the order, or, if the Commissioner of Food and Drugs or the presiding officer denies a request for a hearing, or, if after conducting a regulatory hearing under § 810.11 or completing agency review of a cease distribution and notification order under § 810.12, FDA determines that the order should be amended to require a recall of the device with respect to which the order was issued, FDA shall amend the order to require such a recall. FDA shall amend the order to require such a recall within 15 working days of issuance of a cease distribution and notification order if a regulatory hearing or agency review of the order is not requested, or within 15 working days of denying a request for a hearing, or within 15 working days of completing a regulatory hearing under § 810.11, or within 15 working days of receipt of a written request for review of a cease distribution and notification order under § 810.12.

(b) In a mandatory recall order, FDA may:

(1) Specify that the recall is to extend to the wholesale, retail, or user level;

(2) Specify a timetable in accordance with which the recall is to begin and be completed;

(3) Require the person named in the order to submit to the agency a proposed recall strategy, as described in § 810.14, and periodic reports describing the progress of the mandatory recall, as described in § 810.16; and

(4) Provide the person named in the order with a model recall notification letter that includes the key elements of information that FDA has determined are necessary to inform health professionals and device user facilities.

(c) FDA will not include in a mandatory recall order a requirement for:

(1) Recall of a device from individuals; or

(2) Recall of a device from device user facilities, if FDA determines that the risk of recalling the device from the facilities presents a greater health risk than the health risk of not recalling the device from use, unless the device can

be replaced immediately with an equivalent device.

(d) FDA will include in a mandatory recall order provisions for notification to individuals subject to the risks associated with use of the device. If a significant number of such individuals cannot be identified, FDA may notify such individuals under section 705(b) of the act.

§ 810.14 Cease distribution and notification or mandatory recall strategy.

(a) *General.* The person named in a cease distribution and notification order issued under § 810.10 shall comply with the order, which FDA will fashion as appropriate for the individual circumstances of the case. The person named in a cease distribution and notification order modified under § 810.11(e) or § 810.12(c) or a mandatory recall order issued under § 810.13 shall develop a strategy for complying with the order that is appropriate for the individual circumstances and that takes into account the following factors:

(1) The nature of the serious, adverse health consequences related to the device;

(2) The ease of identifying the device;

(3) The extent to which the risk presented by the device is obvious to a health professional or device user facility; and

(4) The extent to which the device is used by health professionals and device user facilities.

(b) *Submission and review.* (1) The person named in the cease distribution and notification order modified under § 810.11(e) or § 810.12(c) or mandatory recall order shall submit a copy of the proposed strategy to the agency within the timeframe specified in the order.

(2) The agency will review the proposed strategy and make any changes to the strategy that it deems necessary within 7 working days of receipt of the proposed strategy. The person named in the order shall act in accordance with a strategy determined by FDA to be appropriate.

(c) *Elements of the strategy.* A proposed strategy shall meet all of the following requirements:

(1)(i) The person named in the order shall specify the level in the chain of distribution to which the cease distribution and notification order or mandatory recall order is to extend as follows:

(A) Consumer or user level, e.g., health professionals, consignee, or device user facility level, including any intermediate wholesale or retail level; or

(B) Retail level, to the level immediately preceding the consumer or user level, and including any intermediate level; or

(C) Wholesale level.

(ii) The person named in the order shall not recall a device from individuals; and

(iii) The person named in the order shall not recall a device from device user facilities if FDA notifies the person not to do so because of a risk determination under § 810.13(c)(2).

(2) The person named in a recall order shall ensure that the strategy provides for notice to individuals subject to the risks associated with use of the recalled device. The notice may be provided through the individuals' health professionals if FDA determines that such consultation is appropriate and would be the most effective method of notifying patients.

(3) Effectiveness checks by the person named in the order are required to verify that all health professionals, device user facilities, consignees, and individuals, as appropriate, have been notified of the cease distribution and notification order or mandatory recall order and of the need to take appropriate action. The person named in the cease distribution and notification order or the mandatory recall order shall specify in the strategy the method(s) to be used in addition to written communications as required by § 810.15, i.e., personal visits, telephone calls, or a combination thereof to contact all health professionals, device user facilities, consignees, and individuals, as appropriate. The agency may conduct additional audit checks where appropriate.

§ 810.15 Communications concerning a cease distribution and notification or mandatory recall order.

(a) *General.* The person named in a cease distribution and notification order issued under § 810.10 or a mandatory recall order issued under § 810.13 is responsible for promptly notifying each health professional, device user facility, consignee, or individual, as appropriate, of the order. In accordance with § 810.10(c) or § 810.13(b)(4), FDA may provide the person named in the cease distribution and notification or mandatory recall order with a model letter for notifying each health professional, device user facility, consignee, or individual, as appropriate, of the order. However, if FDA does not provide the person named in the cease distribution and notification or mandatory recall order with a model letter, the person named in a cease distribution and notification order issued under § 810.10, or a mandatory recall order issued under § 810.13, is responsible for providing such notification. The purpose of the communication is to convey:

(1) That FDA has found that there is a reasonable probability that use of the device would cause a serious, adverse health consequence or death;

(2) That the person named in the order has ceased distribution of the device;

(3) That health professionals and device user facilities should cease use of the device immediately;

(4) Where appropriate, that the device is subject to a mandatory recall order; and

(5) Specific instructions on what should be done with the device.

(b) *Implementation.* The person named in a cease distribution and notification order, or a mandatory recall order, shall notify the appropriate person(s) of the order by verified written communication, e.g., telegram, mailgram, or fax. The written communication and any envelope in which it is sent or enclosed shall be conspicuously marked, preferably in bold red ink: ''URGENT—[DEVICE CEASE DISTRIBUTION AND NOTIFICATION ORDER] or [MANDATORY DEVICE RECALL ORDER].'' Telephone calls or other personal contacts may be made in addition to, but not as a substitute for, the verified written communication, and shall be documented in an appropriate manner.

(c) *Contents.* The person named in the order shall ensure that the notice of a cease distribution and notification order or mandatory recall order:

(1) Is brief and to the point;

(2) Identifies clearly the device, size, lot number(s), code(s), or serial number(s), and any other pertinent descriptive information to facilitate accurate and immediate identification of the device;

(3) Explains concisely the serious, adverse health consequences that may occur if use of the device were continued;

(4) Provides specific instructions on what should be done with the device;

(5) Provides a ready means for the recipient of the communication to confirm receipt of the communication and to notify the person named in the order of the actions taken in response to the communication. Such means may include, but are not limited to, the return of a postage-paid, self-addressed post card or a toll-free call to the person named in the order; and

(6) Does not contain irrelevant qualifications, promotional materials, or any other statement that may detract from the message.

(d) *Followup communications.* The person named in the cease distribution and notification order or mandatory recall order shall ensure that followup communications are sent to all who fail to respond to the initial communication.

(e) *Responsibility of the recipient.* Health professionals, device user facilities, and consignees who receive a communication concerning a cease distribution and notification order or a mandatory recall order should immediately follow the instructions set forth in the communication. Where appropriate, these recipients should immediately notify their consignees of the order in accordance with paragraphs (b) and (c) of this section.

§ 810.16 Cease distribution and notification or mandatory recall order status reports.

(a) The person named in a cease distribution and notification order issued under § 810.10 or a mandatory recall order issued under § 810.13 shall submit periodic status reports to FDA to enable the agency to assess the person's progress in complying with the order. The frequency of such reports and the agency official to whom such reports shall be submitted will be specified in the order.

(b) Unless otherwise specified in the order, each status report shall contain the following information:

(1) The number and type of health professionals, device user facilities, consignees, or individuals notified about the order and the date and method of notification;

(2) The number and type of health professionals, device user facilities, consignees, or individuals who have responded to the communication and the quantity of the device on hand at these locations at the time they received the communication;

(3) The number and type of health professionals, device user facilities, consignees, or individuals who have not responded to the communication;

(4) The number of devices returned or corrected by each health professional, device user facility, consignee, or individual contacted, and the quantity of products accounted for;

(5) The number and results of effectiveness checks that have been made; and

(6) Estimated timeframes for completion of the requirements of the cease distribution and notification order or mandatory recall order.

(c) The person named in the cease distribution and notification order or recall order may discontinue the submission of status reports when the agency terminates the order in accordance with § 810.17.

§ 810.17 Termination of a cease distribution and notification or mandatory recall order.

(a) The person named in a cease distribution and notification order issued under § 810.10 or a mandatory recall order issued under § 810.13 may request termination of the order by submitting a written request to FDA. The person submitting a request shall certify that he or she has complied in full with all of the requirements of the order and shall include a copy of the most current status report submitted to the agency under § 810.16. A request for termination of a recall order shall include a description of the disposition of the recalled device.

(b) FDA may terminate a cease distribution and notification order issued under § 810.10 or a mandatory recall order issued under § 810.13 when the agency determines that the person named in the order:

(1) Has taken all reasonable efforts to ensure and to verify that all health professionals, device user facilities, consignees, and, where appropriate, individuals have been notified of the cease distribution and notification order, and to verify that they have been instructed to cease use of the device and to take other appropriate action; or

(2) Has removed the device from the market or has corrected the device so that use of the device would not cause serious, adverse health consequences or death.

(c) FDA will provide written notification to the person named in the order when a request for termination of a cease distribution and notification order or a mandatory recall order has been granted or denied. FDA will respond to a written request for termination of a cease distribution and notification or recall order within 30 working days of its receipt.

§ 810.18 Public notice.

The agency will make available to the public in the weekly FDA Enforcement Report a descriptive listing of each new mandatory recall issued under § 810.13. The agency will delay public notification of orders when the agency determines that such notification may cause unnecessary and harmful anxiety in individuals and that initial consultation between individuals and their health professionals is essential.

Dated: November 8, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–29695 Filed 11–19–96; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD07–96–048]

RIN 2115–AE46

Special Local Regulations; Christmas Parade of Boats, Charleston, SC

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: The Coast Guard is establishing permanent special local regulations for the Charleston Christmas Parade of Boats. This one-day event will be held on December 7, 1996, December 13, 1997, December 12, 1998, December 4, 1999, and December 9, 2000, on the Ashley, Wando and Cooper Rivers in Charleston, South Carolina, between 4:30 and 8:30 p.m. Eastern Standard Time (EST). The customary presence of commercial and recreational traffic, and the nature of the event create an extra or unusual hazard on the navigable waters during the event. These regulations are necessary for the safety of life on the navigable waters during the event.

EFFECTIVE DATE: November 20, 1996.

FOR FURTHER INFORMATION CONTACT: Ensign Mike Daponte, Project Officer, Coast Guard Group Charleston, at (803) 724–7621.

SUPPLEMENTARY INFORMATION: In accordance with 5 U.S.C. § 553, the final rule will be made effective in less than 30 days from the date of publication in the Federal Register. Following normal rulemaking procedures will be impracticable, unnecessary, and contrary to the public interest. A notice of proposed rulemaking for this rule was published in the Federal Register (61 FR 188) with a thirty day comment period. The final rule will be made effective in less than thirty days from the date of publication in order to hold the event. During this comment period, no comments were received about this rulemaking.

Regulatory History

On September 26, 1996, the Coast Guard published a notice of proposed rulemaking entitled Charleston Christmas Parade of Boats, Charleston, SC [CGD07–96–048] in the Federal Register (61 FR 188). The comment period ended on October 28, 1996. The Coast Guard received no comments during the notice of proposed rulemaking comment period. A public hearing was not requested and no hearing was held.