50 CFR Chapter VI

PART 600—MAGNUSON ACT PROVISIONS

3. The authority citation for part 600 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

4. In § 600.508, paragraph (f) is revised to read as follows:

§ 600.508 Fishing operations.

* * * * *

(f) *Internal waters.* For FFV's authorized under section 306(c) of the Magnuson-Stevens Act:

(1) Each FFV may engage in fish processing and support of U.S. fishing vessels within the internal waters of that state in compliance with terms and conditions set by the authorizing Governor.

(2) The owner or operator of each FFV must submit weekly reports on the amount of fish received from vessels of the United States and the location(s) where such fish were harvested.

(i) Reports must include:

(A) Vessel identification information for the FFV.

(B) Date of each receipt of fish.

(C) Amount of fish received, by species.

(D) Location(s) from which the fish received were harvested.

(ii) Owners or operators of FFV's processing fish in internal waters under the provisions of this paragraph (f) must request, from the Regional Administrator, the requirements regarding timing and submission of the reports, at least 15 days prior to the first receipt of fish from a vessel of the United States. The Regional Administrator shall stipulate the timing and submission requirements in writing.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 806

[Docket No. 91N–0396]

Medical Devices; Reports of Corrections and Removals

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to establish procedures for implementing the reports of corrections and removals provisions of the Safe Medical Devices Act of 1990 (the SMDA) by requiring that manufacturers, importers, and distributors report promptly to FDA any corrections or removals of a device undertaken to reduce a risk to health posed by the device or to remedy a violation of the Federal Food, Drug, and Cosmetic Act (the act) caused by the device which may present a risk to health. FDA believes that this action is necessary to protect the public health by ensuring that the agency has current and complete information regarding those actions taken to reduce risks to health caused by the devices. Reports of such actions will improve the agency's ability to evaluate device-related problems and to take prompt action against potentially dangerous devices.

DATES: Effective November 17, 1997. Submit written comments on the information collection provisions of this final rule by July 18, 1997.

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

FOR FURTHER INFORMATION CONTACT: Rosa M. Gilmore, Center for Devices and Radiological Health (HFZ–215), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–827–2970.

SUPPLEMENTARY INFORMATION:

I. Background

FDA's reporting and recordkeeping requirements for medical devices reflect a series of amendments to the act (21 U.S.C. 321–394) as follows: (1) The Medical Device Amendments of 1976 (Pub. L. 94–295) (the 1976 amendments) which amended the act to establish the first comprehensive framework for the regulation of medical devices; (2) the SMDA (Pub. L. 101–629), which amended the act to correct noted problems with the implementation and enforcement of the 1976 amendments; and (3) The Medical Device Amendments of 1992 (Pub. L. 102–300) (the 1992 amendments), which amended certain provisions of the act relating to devices.

Section 519(f) of the act (21 U.S.C. 360i(f)), as added by the SMDA, authorizes FDA to issue regulations to require reports and recordkeeping of correction and removal actions taken by device manufacturers, distributors, and importers. Under the final rule, a correction means the 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. 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.

Under section 519(f)(1) of the act, device manufacturers, distributors, and importers are to report promptly to FDA any correction or removal of a device undertaken: (1) To reduce a risk to health posed by the device; or (2) to remedy a violation of the act caused by a device which may present a risk to health. Section 519(f)(1) of the act also requires manufacturers, distributors, and importers to keep records of those corrections and removals that are not required to be reported to FDA. Section 519(f)(2) of the act provides that no report of a correction or removal action under section 519(f)(1) may be required if a report of the correction or removal action is required and has been submitted to FDA under section 519(a), which prescribes rules for reporting and keeping records of certain significant device-related events. Section 519(f)(3) of the act states that the terms ''correction'' and ''removal'' do not include routine servicing.

The final rule provides a mechanism for FDA to receive timely information about potentially dangerous marketed devices by requiring device manufacturers, distributors, and importers to report promptly to FDA any correction or removal of a device undertaken to reduce a risk to health posed by the device, or to remedy a violation of the act caused by the device which may present a risk to health. Section 519(f) of the act was enacted because Congress was concerned that device manufacturers, distributors, and importers were carrying out product corrections or removals without notifying FDA, or without notifying the agency in a timely fashion (H. Rept. 808, 101st Cong., 2d sess. 29 (1990)). Congress explained that industry's failure to report corrections and removals, particularly those undertaken to reduce risks associated with the use of a device, ''denies the agency the opportunity to fulfill its public health responsibilities by evaluating device-related problems and the adequacy of corrective actions'' (S. Rept. 513, 101st Cong., 2d sess. 23 (1990)), and ''has seriously interfered with FDA's ability to take prompt action against potentially dangerous devices'' (H. Rept. 808, 101st Cong., 2d sess. 29 (1990)).

The agency recognizes that Congress did not want to overburden industry or FDA with excessive reporting

requirements and that the reporting requirements apply to the ''more important postmarket actions, excluding those events already reported to the [agency].'' (S. Rept. 513, 101st Cong., 2d sess. 23 (1990)). To ensure that FDA has access to all relevant information on corrections and removals, Congress provided that records be maintained for those corrections and removals that need not be reported.

II. Highlights of the Final Rule

The agency has revised and clarified certain provisions of the final regulation. Further, the agency has narrowed the scope of the regulation to focus more explicitly on those corrections and removals that address more serious risks to health. The most significant changes from the March 23, 1994, proposed rule (59 FR 13828) to establish procedures to implement the reports of corrections and removals provisions of section 519(f) of the act (hereinafter referred to as the March 1994 proposed rule) follow:

1. The definition of ''risk to health'' has been narrowed by revising § 806.2(j) to focus explicitly on those corrections and removals undertaken to mitigate the potential for adverse health consequences. The revised definition of ''risk to health'' tracks the definitions of class I and class II recall in § 7.3(m) (21 CFR 7.3(m)).

2. Section 806.10(e) has been added to allow a device manufacturer, importer, or distributor to disclaim that the submission of a required report of correction or removal is an admission that the device caused or contributed to a death or serious injury.

3. Section 806.10(f) has been added to state clearly that a remedial action that is required and has been reported to the agency under part 803 (21 CFR part 803) (Medical Device Reporting), 21 CFR part 804 (Distributor Reporting), or part 1004 (21 CFR part 1004) (Repurchase, Repairs, or Replacement of Electronic Products) does not have to be resubmitted to the agency as a correction or removal report.

4. FDA has added the definition of ''market withdrawal'' at § 806.2(h) and has amended § 806.1(b)(2) to make clear that market withdrawals are not reportable events.

5. The requirement in § 806.10(b) to submit reports within 10-calendar days of initiating a correction or removal has been changed to 10-working days.

6. The agency has established an effective date of 180 days after publication of the final regulation for submission of reports of corrections and removals.

7. The definition of ''U.S. designated agent'' has been deleted. FDA is reconsidering the duties of foreign manufacturers with respect to reporting under this rule and under part 803 and may propose a new rule to address this issue in the future.

FDA believes that with these revisions, the final rule incorporates reasonable requirements that can be implemented by the regulated industry without unnecessary burden.

III. Summary and Analysis of Comments and FDA's Response

The March 1994 proposed rule proposed to establish procedures to implement the reports of corrections and removals provisions of section 519(f) of the act. FDA received 33 comments and 2 requests for an extension of the comment period in response to the March 1994 proposed rule. This total number represents comments received from manufacturers, distributors, trade associations, attorneys, and one hospital. For the most part, each comment addressed various aspects of the March 1994 proposed rule. Several of the comments stated that the March 1994 proposed rule was overly broad in scope, required the submission of unnecessary data, and imposed undue burdens on FDA and industry. Several comments also cited FDA's failure to address in the preamble the voluntary recall regulation, which was published in the **Federal Register** of June 16, 1978 (43 FR 26202), and the medical device reporting (MDR) regulation, which was published in the **Federal Register** of December 11, 1995 (60 FR 63578). Some of the comments stated that the definitions of certain regulatory terms lacked clarity. Other comments expressed concern regarding public disclosure of trade secrets, and confidential commercial and financial information in reports of corrections and removals submitted to FDA. FDA did not extend the comment period. The comments and FDA's responses are summarized below.

1. Several comments stated that the proposed requirements for reports of corrections and removals should clarify the relationship between the reports of corrections and removals regulation and FDA's voluntary recall policy in part 7 (21 CFR part 7). FDA notes that the recall policy (including product corrections) in part 7 was not addressed in the preamble to the March 1994 proposed rule.

In the voluntary recall regulation, FDA established the agency's policy and procedures for voluntary product recalls. This final notice was intended to provide guidance to manufacturers and distributors of all products regulated by FDA so that they could more effectively discharge their recall responsibilities. The voluntary guidelines apply to all FDA-regulated products (i.e. food, including animal feed; drugs; medical devices, including in vitro diagnostic products; cosmetics; and biological products intended for human use) except electronic products subject to the Radiation Control for Health and Safety Act (RCHSA) (Pub. L. 90–602) that are not medical devices, and may be undertaken at any time by manufacturers and distributors, or at the request of FDA. These voluntary guidelines remain in effect and will supplement the reports of correction and removal provisions of section 519(f) of the act. If a report of correction or removal is required under part 806 (21 CFR part 806), it must be submitted as provided in § 806.10. If a report is not required under part 806, an entity may voluntarily report under part 7. The definition of ''risk to health'' in this rule (§ 806.2(j)) tracks the definitions of class I and class II recall in § 7.3(m). The effect of using the same language in part 806 is to require reports of corrections and removals for class I and class II recalls. Under part 806, manufacturers, importers, and distributors must keep records of events categorized as class III recalls under part 7.

Section 518(e) of the act (21 U.S.C. 360h(e)) provides FDA with the authority to initiate mandatory recall actions if there is a reasonable probability that a device intended for human use would cause serious adverse health consequences or death. In the **Federal Register** of November 20, 1996 (61 FR 59004), FDA published a final rule requiring recall of medical devices under some circumstances. Any corrective or removal action initiated by an FDA order under section 518(e) of the act need not be reported under part 806 because FDA will already be aware that the action is taking place. In such cases, reporting or notification requirements of the section 518(e) order and the recall regulation will be applicable.

2. Comments stated that this rule duplicates the requirements of the MDR regulation (part 803). Other comments stated that it is unclear which events should be reported under the MDR regulation.

FDA agrees that the relationship between this final rule and the MDR regulation warrants clarification so as to avoid unnecessary duplication. Indeed, section 519(f)(2) of the act prohibits FDA from requiring a report of correction or removal, if that same

information has been required and has been submitted under MDR.

Generally, there is expected to be little overlap between these reporting requirements. This is because MDR's are based on adverse events that have occurred (i.e., deaths, serious injuries, and malfunctions) regardless of whether a remedial action (i.e., correction or removal) has been undertaken by the manufacturer or distributor. Moreover, the MDR report, which is tied to the adverse event itself and its possible association with the device, will only rarely address any remedial action taken by the manufacturer because, in most cases, no such remedial action has yet occurred.

The primary area where such overlap between the final rule and MDR would be expected is with the 5-day MDR report. This is because 5-day MDR reports are required within 5 days of the submitter becoming aware that an MDR reportable event (i.e., death, serious injury, or malfunction) *requires remedial action* to prevent an unreasonable risk of substantial harm to the public health (§ 803.55). Thus, by linking the 5-day MDR reports to the need for remedial action, information concerning the correction or removal will necessarily be submitted under MDR and will not need to be resubmitted under part 806. FDA has modified the final rule to reflect this (§ 806.10(f)).

In addition, in those rare cases where the routine MDR reports submitted to FDA (30-day reports for manufacturers and 10-day reports for distributors) are required to and do contain information on the remedial actions taken (i.e., corrections or removals), then no additional report under this final rule needs to be submitted to the agency.

FDA notes that, under regulations issued to implement the RCHSA, the equivalent of a report of a correction or removal is required under part 1004 for electronic products which may also be medical devices. Part 1004 requires that, if an electronic product has a defect or fails to meet an applicable Federal performance standard, the manufacturer shall, repair, replace, or refund the cost of the electronic product. Devices for which Federal standards are currently in place under the RCHSA include x-ray equipment, fluoroscopy equipment, magnetic resonance imaging devices, medical lasers, and ultrasound devices.

FDA believes that the information that is required by part 1004 is sufficient notice to FDA of a correction or removal. Furthermore, manufacturers of these products are familiar with the reporting requirements of part 1004. Therefore, on its own initiative, FDA is modifying § 806.10(e) to state that, if a report is required and is submitted under part 1004 for a correction or removal that would otherwise be required to be reported under part 806, no report under part 806 is required.

3. Comments questioned FDA's authority to review any correction or removal report to determine if the correction or removal action should be extended to other units of the same device, other products of the same manufacturer or distributor, or similar products of other manufacturers and distributors.

FDA believes that it is appropriate and necessary, and in the interest of the public health, for FDA to review reports of corrections and removals to determine if any further remedial action such as a recall or safety alert is required, and to further determine if there is a need to extend the correction or removal action to other units of the same device, other products of the same manufacturer, distributor, or importer, or similar products of other manufacturers, distributors, or importers, which may present a similar risk to health.

4. Some of the comments received in response to the March 1994 proposed rule for reports of corrections and removals stated that manufacturers of general purpose articles, such as chemical reagents and laboratory equipment, are not subject to medical device regulations.

Under § 807.65(c) (21 CFR 807.65(c)), general purpose articles whose uses are generally known by persons trained in their use, unless labeled or promoted for medical use, are exempt from registration, listing, and premarket notification requirements. However, unless exempted by regulation, general purpose articles that are medical devices are subject to section 519(f) of the act and to the requirements of this rule.

The March 1994 proposed rule at § 806.1(b)(3) exempted certain actions undertaken by manufacturers of general purpose articles that were already exempted from reporting under § 806.1(b)(1). The exemption that formerly appeared at § 806.1(b)(3) does not appear in the final rule because it is redundant and unnecessary.

5. Comments objected that the March 1994 proposed rule does not differentiate removals done solely upon customer request from other removals.

Removals done solely upon customer request (i.e., overstock, discontinued use of the item, order error, old stock, not current design, or perceived issues with specific lots) that are not performed to reduce a risk to health posed by the device, or to remedy a violation of the act caused by the device that may present a risk to health, are not removals within the meaning of section 519(f)(1) of the act. FDA has amended § 806.2 to include the definition of ''market withdrawal'' and § 806.1(b)(2) to make clear that market withdrawals are not reportable events. The definition of market withdrawal in § 806.2(h) tracks the definition in the voluntary recall provisions in § 7.3(j). The example in § 7.3(j) of ''routine equipment adjustments and repairs'' is not included in new § 806.2(h) because it would be redundant to the definition of ''routine servicing'' in § 806.2(k).

6. Comments stated that it would be redundant to require convenience kit manufacturers to report when the supplier of the component initiates a correction or removal; to do so would be redundant and no additional value would be added to the process.

FDA agrees that duplicate reports would be redundant, but disagrees that the rule requires duplicate reports. Only the person who initiates the correction or removal is required to report.

7. Comments stated that the manufacturer should not be required to report if a manufacturer discovers after removing or correcting a medical device that the device did not pose a risk to health or that the risk posed was no greater than the risk described on the labeling of the device.

A manufacturer, distributor, or importer that initiates a correction or removal of a device to reduce a risk to health or remedy a violation of the act that could present a risk to health must submit a report to FDA within 10-working days of initiation of the action. In most cases, if the action has been completed, it should have been reported. The only way the action would be exempt from reporting within the required 10-working days is if it was determined by the manufacturer, distributor, or importer during that 10-day period that the device did not present a risk to health, or there was no violation of the act that could present a risk to health. After a report is received by the agency, if FDA determines that there is no health risk, or violation of the act that could present a risk to health, FDA would not classify the action as a safety alert or as a recall under part 7, but more likely as a market withdrawal.

8. Comments stated that distributors may not have the capacity to make the determination as to whether a given action is reportable. Other comments suggested that the reports of corrections and removals should not apply to drug wholesalers that distribute devices

because they have neither the authority nor the expertise to determine health risk or to undertake any corrections or removals of a manufacturer's product. Some comments stated that the definition of distributor in the March 1994 proposed rule is too broad.

It is clear from the statute that Congress intended that distributors be required to submit reports of corrections and removals if they initiate a correction or removal action. The agency believes that the definition of distributor in § 806.2(f) is sufficient. Narrowing this definition would prevent the agency from monitoring corrective action taken concerning adulterated or misbranded devices.

9. Comments objected that routine reporting by distributors would disproportionately utilize the agency's resources.

Section 519(f) of the act only requires distributors to report corrective or removal actions if they initiate the action and only one report for each correction or removal is required. Therefore, FDA does not believe that distributor reporting will disproportionately use the agency's resources.

10. Comments said that device rental companies should be defined as multiple distributors and not manufacturers.

The rule does not define rental companies as manufacturers. Rather, companies that rent devices would fall within the definition of ''distributor'' (§ 806.2(f)) for the purposes of this rule. Manufacturers and distributors are subject to the same requirements under this rule to report and keep records of corrections and removals initiated by them.

11. Some comments stated that the scope of the March 1994 proposed rule for reports of corrections and removals should apply to entities that refurbish or recondition a device for resale.

Under section 519(f) of the act, the requirement for reporting corrections and removals applies to any manufacturer, importer, or distributor of a device, which would include a refurbisher and a reconditioner. Accordingly, if a refurbisher or refinisher of a device initiates a correction or removal, that refurbisher or reconditioner is responsible for reporting under part 806.

12. Some comments stated that the reports of corrections and removals regulation should be written to exclude some medical devices which clearly pose no threat to the safety of the patient in case of label mixups.

FDA believes that the request to exclude some medical devices which clearly pose no threat to the safety of the patient in case of label mixups is neither appropriate nor necessary. If a label mixup does not present a risk to the public health, no report is required.

13. Comments suggested that the proposed regulation should be narrowed so as to focus more explicitly on those removals and corrections undertaken to mitigate the potential for serious illness or serious injury. Other comments stated that the threshold for reporting corrections and removals is too low.

The agency believes that it is appropriate to narrow the scope of the regulation to focus more explicitly on those corrections and removals initiated to mitigate the potential for adverse health consequences. As discussed elsewhere in this regulation, FDA has revised the definition of ''risk to health'' (§ 806.2(j)) to enable the agency to focus its resources on more significant health problems.

14. Comments said that FDA should add the following explicit examples of potential corrections and removals that are not intended to reduce a risk to health posed by the device or remedy a violation of the act: (1) When no injury has been, or is likely to be, associated with the event; (2) when a product has reached the end of its useful life; (3) when a device is returned to its original specifications due to extensive use; (4) when no cause for the device failure can be found following failure investigation; (5) where the withdrawal is for the purpose of retracting a new product line and/or upgrading the device to a more recent version; (6) where a request is made to return product for a complaint or MDR evaluation; or (7) when a device from a batch/lot is needed to aid in the investigation of a complaint about the same batch/lot.

The agency believes that it is not necessary to provide explicit examples of potential reports of corrections and removals that are not intended to reduce a risk to health posed by the device or remedy a violation of the act caused by the device that may present a risk to health. A firm may routinely correct or remove its devices in the marketplace or under its control for various reasons other than to reduce a risk to health or remedy a violation of the act that may present a risk to health. However, in response to these comments, FDA has added the definition of ''stock recovery'' at § 806.2(l) and exempted actions meeting this definition from the reporting requirements at § 806.1(b)(4). The definition of ''stock recovery'' in § 806.2(l) tracks the definition in the voluntary recall provisions in § 7.3(k). Only actions taken by a manufacturer can meet the definition of ''stock recovery.''

15. Comments said that the scope of the March 1994 proposed rule should be broadened to include a definition of ''device enhancement''.

The agency does not believe that it is necessary to define ''device enhancement''. If a correction or removal is initiated in order to enhance a device in the absence of a risk to health, no report is required. The central question is whether there is a risk to health and not whether the device is enhanced. Section 806.1(b) makes it clear that an action taken to improve a device in the absence of a risk to health is not a reportable event.

16. Comments said that the requirement that only one report be submitted for each reportable event means that a reportable event is a specific correction or removal program for a defined population of devices rather than a correction or removal of an individual device. Other comments said that the proposed regulation appears to require reporting whenever a particular device is inspected, adjusted, or repaired in an identical way more than once even when the triggering events are random, are separated in time, and no program of repair or correction is in progress or is needed.

FDA agrees that generally, a single correction or removal that involves more than one device requires only one report. However, when the triggering events for removals or corrections are the same but are separated in time, for example, when consecutive lots of a product with the same defect are not released at the same time, separate reports will have to be made for each event unless the timing is such that more than one event can be reported at once, given the time period for reporting in this regulation. FDA encourages manufacturers, distributors, and importers to consider whether it would be appropriate to extend removal or corrective actions performed in response to one event to other units of the same device or similar devices and, in some cases, this type of investigation may be required under part 820 (21 CFR part 820). If multiple repairs of the same or similar devices are undertaken as part of a program of repair, the triggering incident and the entire program of repair can be submitted as one report. The agency will require amendments when additional devices, lots, and batches are being added to the same corrections or removal. This approach provides a more efficient and effective procedure for reporting actions that should be considered together. FDA has

added a new § 806.10(d) to provide for the submission of such amendments.

17. One comment states that a ''bug list'' distributed by device manufacturers to customers advising them of problems associated with software equipment used to run work stations could be considered a correction to software.

A manufacturer, importer, or distributor that undertakes a corrective or removal action for computer software that is considered a medical device must submit a report of such action to FDA. If the action is taken to reduce a risk to health or to remedy a violation of the act that could present a risk to health caused by computerized software that comes within the definition of a device, a report must be submitted; however, it is not likely that a ''bug list'' would be considered a removal. A ''bug list'' could be considered a correction if it constitutes relabeling, but again, would only be reportable if it was undertaken to reduce a risk to health or to remedy a violation of the act that could present a risk to health.

18. Some comments stated that the definition of risk to health was too broad; that the definition of ''risk to health'' should not include the terms ''or error in the use of the device''; that the definition of ''risk to health'' should include ''error in the use of the device''; and that to impose these additional documentation and reporting requirements upon manufacturers adds a significant regulatory burden.

FDA agrees that the definition of risk to health in the March 1994 proposed rule is too broad. The agency has revised the definition of ''risk to health'' at § 806.2(j) to mean (1) a reasonable probability that the use of, or exposure to, the product will cause serious adverse health consequences or death, or (2) that use of, or exposure to, the product may cause temporary or medically reversible adverse health consequences, or an outcome where the probability of serious adverse health consequences is remote. The practical effect of adopting this revised definition is to require reports of removals and corrections for those corrective actions that would be classified as class I or class II recalls under § 7.3(m). Moreover, the agency intends for ''serious adverse health consequences'' to have the same meaning as ''serious injury'' under the MDR rule. At § 803.3(aa)(1), the MDR rule defines serious injury to mean an illness or injury that (1) is life-threatening; (2) results in permanent impairment of a body function or permanent damage to a body structure; or (3) necessitates medical or surgical intervention to preclude permanent damage to a body structure.

This definition allows FDA to allocate its resources efficiently and precludes an unnecessary burden on manufacturers of reporting requirements for extremely remote, trivial risks to the public health. However, a correction or removal undertaken to alleviate a risk to health as defined by § 806.2(j) must be reported under this section even if caused by user error. Reports about corrections or removals based on user error are important to FDA's ability to evaluate the problems with devices and to take prompt action against potentially dangerous devices.

19. Comments said that the phrase ''to remedy a violation of the act caused by the device which may present a risk to health'' should be further clarified.

Action taken to remedy a violation of the act means any action taken to bring a device that was not in compliance with any provision of the act into compliance or to prevent a noncompliance before it occurs.

20. Comments said that the definitions of the terms ''correction'' and ''removal'' are overly broad and would require reports to FDA of thousands of service reports when a medical device is repaired. Further, comments said that the definition of routine servicing is extremely vague and open to subjective interpretation, while others said that this definition was overly restricted and unrealistic.

FDA believes that the definitions of the terms ''correction'' and ''removal'' are appropriate in scope. It is important to emphasize that, under the final rule, a report to FDA is required only when a specific action is taken to reduce a risk to health or to remedy a violation of the act that could result in a risk to health. Section 519(f)(3) of the act states that the terms ''correction'' and ''removal'' do not include routine servicing. As defined in § 806.2(k) an action is considered ''routine servicing'' if it is conducted in accordance with a maintenance schedule for a device, or if it is a repair, adjustment, or replacement of parts in response to normal wear and tear of a device. An action is required to be reported only if it is specifically initiated to reduce a risk to health or remedy a violation of the act that could result in a risk to health. Under § 806.1(b)(2), routine servicing is exempt from the reporting requirements of this regulation.

21. Comments said that the definition of consignee is overly broad.

FDA does not agree with these comments. FDA believes that the definition of ''consignee'' should be sufficiently broad to protect the public health. A correction or removal need only reach the level of consignee appropriate for the situation.

22. A comment said that FDA should clarify the definition of ''U.S. designated agent''.

The term ''U.S. designated agent'' was first introduced in the MDR regulation (§ 803.3(n)). In the **Federal Register** of July 23, 1996 (61 FR 38346), FDA stayed the effective date of the U.S. designated agent provisions of the MDR rule and announced that it intended to reconsider reporting by foreign manufacturers and issue a new proposal in the near future. In keeping with that announcement, FDA has deleted the definition of ''U.S. designated agent'' that appeared in the March 1994 proposed rule at § 806.2(g)(4), from the reports of corrections and removals regulation. Foreign firms meeting the definition of ''manufacturer,'' ''distributor,'' or ''importer'' are responsible for submitting their own reports of corrections and removals involving devices imported into the United States. Failure to do so will result in their devices being adulterated under section 502(t) of the act (21 U.S.C. 352(t)) and may cause their devices to be refused admission for import under section 801(a) of the act (21 U.S.C. 381(a)).

23. One comment stated that FDA should make the recordkeeping requirements advisory rather than mandatory. Another comment stated that the preamble is confusing in that it implies without stating that entities must supply justification for when reporting is not required.

FDA disagrees with these comments. Section 519(f) of the act directs FDA to issue regulations to require reporting and recordkeeping of correction and removal actions. Section 519(f)(1) of the act requires manufacturers, distributors, and importers to keep records of those corrections and removals that are not required to be reported to FDA (see S. Rept. 513, 101st Cong., 2d sess. 23 (1990)). Section 806.20(c)(4) requires explicitly that entities include the justification for not reporting a correction or removal in the records required by this rule. These records will be used by FDA to audit the manufacturer's determination that a report of correction or removal was not required. Similarly, § 820.198 requires manufacturers to keep records of evaluations of complaints whether or not they are reportable under the MDR regulation.

24. Several comments stated that the 10-calendar days in § 806.10(b) within which to submit a report of a correction or removal is not enough time. Some

comments stated that the agency should clarify when a correction or removal is considered to be ''initiated''.

FDA agrees with these comments. In order to allow sufficient time for preparation of complete reports, FDA has extended the reporting period to 10-working days. This will allow for a sufficient time for reporting when holidays or weekends intervene. However, the agency recognizes that, on rare occasions, a manufacturer or distributor will not be able to gather all the information required by § 806.10 to complete a report. Therefore, FDA has revised the regulation by including § 806.10(b)(13) to allow manufacturers and distributors to identify information that is not available, provided that they state when it will be available.

Although the SMDA does not specifically define the term ''initiation'' or ''initiating'', FDA believes that the initiation or initiating of a correction or removal is that moment in time when a firm makes the first contact within or outside the firm that begins the correction or removal action.

25. One comment stated that the information manufacturers would be required to report is far in excess of that which FDA needs for a reporting program, especially in light of the many other controls and reporting programs already in effect that require companies to maintain records and/or make reports about the same type of information. Another comment stated that the criteria for submission of reports of corrections and removals are too subjective and may be difficult to apply in actual practice.

FDA agrees with these comments and, as noted above, has narrowed the definition of ''risk to health.'' The final rule, as revised, applies basically the criteria for class I and class II recalls used successfully by FDA for more than 20 years under part 7.

26. One comment stated that a form for reporting corrections and removals would be useful, particularly if it served as a checklist of required information but allowed flexibility in providing the information. The comment also stated that it would be helpful if electronic or disc submissions were possible. One comment stated that a form would be impractical as it would not allow the flexibility necessary to accommodate various needs. One comment developed and submitted a form for use by the agency.

In the March 1994 proposed rule, FDA solicited comments regarding whether it would be desirable to develop a form to collect reports of correction and removal data. FDA has determined that a form is not necessary. FDA believes that industry and the agency have more flexibility without a form without sacrificing good information management practices.

In the **Federal Register** of March 20, 1997 (62 FR 13430), FDA published a final rule that will, under certain circumstances, permit the submission of electronic records, electronic signatures, and handwritten signatures executed to electronic records as generally equivalent to paper records and handwritten signatures executed on paper. The rule will apply to records that are called for in title 21 of the Code of Federal Regulations (CFR) when submitted in electronic form. The intended effect of the March 1994 proposed rule is to permit use of electronic technologies in a manner that is consistent with FDA's overall mission and that preserves the integrity of the agency's enforcement activities.

27. One comment stated that a manufacturer may be admitting product liability if the manufacturer is required to submit a report for a correction or removal of a device when the regulation requiring the report is based upon ''risk to health''. The comment stated that the proposed regulation should be amended to allow a manufacturer to disclaim the admission of risk to health associated with a device by the mere submission of this required report.

In response to the comment, FDA has added § 806.10(e) to the final rule stating that a report of information submitted by a manufacturer, distributor, or importer (and any release by FDA of that report or information) does not necessarily reflect a conclusion by the manufacturer, importer, distributor, or FDA that the report or information constitutes an admission that the device caused or contributed to a death or serious injury. A manufacturer, distributor, or importer need not admit, and may deny, that the report or information submitted under this section constitutes an admission that the device caused or contributed to a death or serious injury.

28. Some comments stated that the term ''complete'' is subjective and should be deleted from § 806.10(c)(7), which required ''A complete description of the event(s) giving rise to the information reported and the corrective or removal actions that have been, and are expected to be, taken'' (emphasis added), and § 806.20(b)(3), which required ''A complete description of the event giving rise to the information reported and the corrective or removal action that has been, and is expected to be taken.''

FDA agrees with these comments. The term ''complete'' has been deleted from these sections of the regulation.

29. One comment stated that the word ''inspection'' should be deleted from the definition of correction. According to this comment, the act of inspecting is not, per se, an event which corrects a device. The comment said that, while an action of correction could result from an inspection event, the process of determining if a correction is warranted should not be a reportable event under part 806.

FDA agrees an inspection that is conducted before a determination that a public health risk exists is not a reportable event. However, FDA believes that an inspection that is initiated as a result of a public health risk is a correction. The term ''inspection (including patient monitoring)'' is included in the definition of ''correction'' in § 7.3. FDA has in the past classified firms' inspections that were conducted to determine which device contained a defective component as recall actions, especially when a firm failed to maintain adequate records to determine which devices were manufactured with a possible defect, or which consignees received defective devices.

30. Some comments stated that the proposed requirement with regard to the number scheme for ''C'' (correction) and ''R'' (removal) type reports is not clear. Another comment stated that FDA has exceeded the scope of its statutory authority in mandating a specific reporting format for reports of corrections and removals. Other comments stated that manufacturers should be provided with the option of designating their own report numbers. Another comment stated that requiring the creation of an 18 character alpha-numeric field for computer data bases to identify, track, and retrieve associated information in the correction or removal report number section adds unnecessary additional requirements to the recordkeeping task for manufacturers, and that perhaps the existing unique sequence number that each manufacturer uses to identify their product complaints should be adequate.

FDA believes that the number scheme for ''C'' (corrections) and ''R'' (removal) type reports should be clarified, and has clarified the numbering system in § 806.10(c)(1). FDA does not believe that it has exceeded its statutory authority. A uniform numbering system for reports of corrections and removals will assist the agency, in filing, organizing, and retrieving reports of corrections and removals. By facilitating the agency's orderly processing of reports, a uniform numbering system will ensure the agency's prompt and efficient attention to the information submitted. Moreover,

as discussed above in response to comment 26, the agency has published a rule that will permit electronic submissions of some reports. A uniform numbering system will greatly simplify the storage and retrieval of electronic reports.

31. One comment stated that the current practice is for manufacturers or distributors reporting a recall action to report to the FDA district office in the area where the manufacturer's or distributor's site conducting the recall is located. The comment stated that a report of correction or removal should be submitted to the FDA district office with jurisdiction over the location of the manufacturer that is conducting the correction/removal action. Some comments stated that the reports of corrections and removals should be submitted to the FDA district office in which the facility coordinating the correction or removal is located. Other comments stated that reports should be made to FDA headquarters rather than to each district office.

FDA believes that reports of corrections and removals should be sent to the district office for the district in which the reporting facility is located, whether it is the distributor's site, manufacturing site, or the corporate office. The district office in the reporting facility's district will have direct contact with the reporting firm, as it does now with recalling firms, and will therefore be able to monitor the firm's actions more easily, and in a timely fashion. Manufacturers, distributors, and importers are expected to follow company policy for submission of reports of actions involving multiple operations. For foreign firms, reports should be made to the district office of the district in which any initial distributor of the device in the United States is located.

32. One comment stated that the March 1994 proposed rule will impose significant costs on manufacturers and distributors of medical devices. Some comments stated that the projection of no more than 800 reports per year grossly underestimates the likely number. Other comments stated that the cost is underestimated.

FDA has revised aspects of the final rule, in particular the definition of ''risk to health,'' as discussed above. FDA believes that these revisions substantially narrow the definition of reportable events. Based on the number of voluntary recalls reported to FDA since 1990 and the number of unreported recalls identified through FDA's investigations, the estimate provided in the March 1994 proposed rule for 800 reports should be adjusted slightly upward to 880. The agency typically uncovers 40 unreported events annually. FDA's estimates are discussed in more detail in sections IV and V of this document. FDA believes that the information it has used to project the number of reports is reliable and that 800 to 880 reports is a rational, well-justified estimate of the number of reports the agency will receive.

33. Some comments expressed concern over confidentiality of the reports of corrections and removals submitted to FDA. For the most part, comments recommended that FDA delete the names, addressees, and telephone numbers of consignees prior to public disclosure of reports of corrections and removals.

FDA is aware of confidentiality concerns. For the most part, FDA is required under the Freedom of Information Act (FOIA) (5 U.S.C. 552), to make reports of corrections and removals publicly available. The public availability of such reports is governed by the FOIA and part 20 (21 CFR part 20). Before a report is made publicly available in accordance with the FOIA and part 20, FDA will delete from the report information whose disclosure would constitute an invasion of personal privacy (see 5 U.S.C. 552(b)(6); § 20.63), or information that constitutes trade secret or confidential commercial or financial information (see 5 U.S.C. 552(b)(4); § 20.61). The public availability of the reports required by this regulation is discussed in § 806.40.

II. Enforcement

Violations of this rule, which is issued under the authority of sections 502, 510, 519, 520, 701, and 704 of the act (21 U.S.C. sections 352, 360, 360i, 360j, 371, and 374), will result in committing one or more of the following violations of section 301 of the act:

1. Section 301(e) of the act (21 U.S.C. 331(e)), which prohibits, among other things, the failure to establish or maintain any record, or make any report, required under section 519 of the act or the refusal to permit officers or employees designated by FDA to have access to or verification or copying of any such required record.

2. Section 301(f) of the act, which prohibits the refusal to permit entry or inspection as authorized by section 704 of the act (21 U.S.C. 374). Section 704(e) of the act requires every person required under section 519 of the act to maintain records and every person who is in charge or custody of such records, upon request of an officer or employee designated by FDA, to permit such officer or employee to have access to, and copy and verify, such records.

3. Section 301(q) of the act, which prohibits, among other things, the failure or refusal to furnish any material or information required by or under section 519 of the act or the submission of such a report that is false or misleading in any respect.

In addition, section 502(t)(2) of the act deems a device to be misbranded if there was a failure or refusal to furnish any material or information required by or under section 519 of the act respecting the device. Section 301(a), (b), (c), (g), and (k) of the act prohibit several actions with respect to misbranded devices. Persons who violate section 301 of the act may be restrained, under section 302 of the act (21 U.S.C. 332), or may be imprisoned or fined under section 303 of the act (21 U.S.C. 333). FDA may also seize misbranded devices under section 304 of the act (21 U.S.C. 334).

The SMDA also added section 303(f) to the act, which provides for the first time that any person who fails to demonstrate substantial compliance with section 519(f) of the act may be subject to civil penalties. These penalties do not apply to any person who commits minor violations of section 519(f) of the act with respect to correction reports, if such person demonstrates substantial compliance with section 519(f). A civil penalty may not exceed $15,000 for a single violation, and may not exceed $1,000,000 for all such violations adjudicated in a single proceeding.

III. Environmental Impact

The agency has determined that this action falls within the category of actions described in 21 CFR 25.24(a)(8) which do not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). 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. If a rule has a significant

economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of the rule on small entities.

The final rule requires medical device manufacturers, importers, and distributors to report promptly to FDA any correction or removal of a device undertaken to reduce a risk to health posed by the device or to remedy a violation of the act that could present a risk to health caused by the device. FDA currently receives, as voluntary reports under part 7, an estimated 800 reports of corrections and removals each year and typically uncovers an additional 40 unreported events. Factoring in an additional 40 reports that FDA does not uncover, FDA estimates that it will receive about 880 reports of corrections and removals under § 806.10 annually and that entities will be required to keep records of an additional 440 events. There are more than 20,000 manufacturers, importers, and distributors of medical devices subject to this rule. The large majority of entities will not be required to submit any reports in any particular year, and, most likely, only the largest entities would be required to report more than 1 or 2 events in any year. Because of the relatively small incremental increase in reporting and recordkeeping required by this rule and the relatively modest costs attendant upon that increase, the Commissioner of Food and Drugs certifies that the final rule will not have a significant economic impact on a substantial number of small entities. The factual basis for this certification is the estimate that the implementation of the corrections and removals provision will require approximately 880 reports per year and recordkeeping of approximately 440 events. Therefore, under the Regulatory Flexibility Act, no further analysis is required. FDA has sent its certification and the factual basis for it set out above to the Chief Counsel for Advocacy, Small Business Administration.

V. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: Reports of Corrections and Removals for Manufacturers, Importers, and Distributors of Medical Devices.

Description: This regulation establishes the procedures for implementing the reports of corrections and removals provisions of the SMDA. The purpose of this regulation is to protect the public health by permitting FDA to promptly receive information about devices that have been corrected or removed to avert a risk to health or to remedy a violation of the act that could present a risk to health. The collection of this information is required by section 519(f) of the act.

Description of Respondents: Businesses or other for profit organizations.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
806.10	880	1	880	10	8,800

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
806.20	440	1	440	10	4,400

There are no capital or operating and maintenance costs expected as a result of this final rule.

Although the March 1994 proposed rule provided a 90-day comment period under the Paperwork Reduction Act of 1980, and this final rule is based on comments received, the proposed rule has not been previously available to OMB for review. FDA 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 proposed 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 use of automated collection techniques, when appropriate, and other forms of information technology.

Although the reporting burden estimate in the March 1994 proposed rule was 8,000 hours, based on an evaluation of the agency's recent experience with the voluntary recall rule and the MDR rule, FDA now estimates that the annual reporting burden for respondents in § 806.10 is 8,800 hours. The adjusted total estimated annual recordkeeping burden is now 4,400 hours (Table 1).

Individuals and organizations desiring to submit comments regarding FDA's burden estimates or any aspects of the information collection provisions of the final rule should do so by July 18, 1997. These comments should be directed to FDA's Dockets Management Branch (address above).

At the close of the 60-day comment period, FDA will review the comments received, revise the information collection provisions as necessary, and submit these provisions to OMB for review. FDA will publish a notice in the **Federal Register** when the information collection provisions are submitted to OMB, and an opportunity for public comment to OMB will be provided at that time. 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 provisions. 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.

List of Subjects in 21 CFR Part 806

Corrections and removals, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 806 is added to read as follows:

PART 806—MEDICAL DEVICE CORRECTIONS AND REMOVALS

Subpart A—General Provisions

Sec.
806.1 Scope.
806.2 Definitions.

Subpart B—Reports and Records

806.10 Reports of corrections and removals.
806.20 Records of corrections and removals not required to be reported.
806.30 FDA access to records.
806.40 Public availability of reports.

Authority: Secs. 502, 510, 519, 520, 701, and 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352, 360, 360i, 360j, 371, 374).

Subpart A—General Provisions

§ 806.1 Scope.

(a) This part implements the provisions of section 519(f) of the Federal Food, Drug, and Cosmetic Act (the act) requiring device manufacturers and distributors, including importers, to report promptly to the Food and Drug Administration (FDA) certain actions concerning device corrections and removals, and to maintain records of all corrections and removals regardless of whether such corrections and removals are required to be reported to FDA.

(b) The following actions are exempt from the reporting requirements of this part:

(1) Actions undertaken by device manufacturers and distributors, including importers, to improve the performance or quality of a device but that do not reduce a risk to health posed by the device or remedy a violation of the act caused by the device.

(2) Market withdrawals as defined in § 806.2(h).

(3) Routine servicing as defined in § 806.2(k).

(4) Stock recoveries as defined in § 806.2(l).

§ 806.2 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) ''Consignee'' means any person or firm that has received, purchased, or used a device subject to correction or removal.

(d) ''Correction'' means the 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.

(e) ''Correction or removal report number'' means the number that uniquely identifies each report submitted.

(f) ''Distributor'' means any person, including any person who imports a device into the United States, who furthers the marketing of a device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user, but who does not repackage or otherwise change the container, wrapper, or labeling of the device or device package.

(g) ''Manufacturer'' means any person who manufactures, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedures. The term includes any person who:

(1) Repackages or otherwise changes the container, wrapper, or labeling of a device in furtherance of the distribution of the device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user or consumer;

(2) Initiates specifications for devices that are manufactured by a second party for subsequent distribution by the person initiating the specifications; or

(3) Manufactures components or accessories which are devices that are ready to be used and are intended to be commercially distributed and are intended to be used as is, or are processed by a licensed practitioner or other qualified person to meet the needs of a particular patient.

(h) ''Market withdrawal'' means a correction or removal of a distributed device that involves a minor violation of the act that would not be subject to legal action by FDA or that involves no violation of the act, e.g., normal stock rotation practices.

(i) ''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.

(j) ''Risk to health'' means

(1) A reasonable probability that use of, or exposure to, the product will cause serious adverse health consequences or death; or

(2) That use of, or exposure to, the product may cause temporary or medically reversible adverse health consequences, or an outcome where the probability of serious adverse health consequences is remote.

(k) ''Routine servicing'' means any regularly scheduled maintenance of a device, including the replacement of parts at the end of their normal life expectancy, e.g., calibration, replacement of batteries, and responses to normal wear and tear. Repairs of an unexpected nature, replacement of parts earlier than their normal life expectancy, or identical repairs or replacements of multiple units of a device are not routine servicing.

(l) ''Stock recovery'' means the correction or removal of a device that has not been marketed or that has not left the direct control of the manufacturer, i.e., the device is located on the premises owned, or under the control of, the manufacturer, and no portion of the lot, model, code, or other relevant unit involved in the corrective or removal action has been released for sale or use.

Subpart B—Reports and Records

§ 806.10 Reports of corrections and removals.

(a) Each device manufacturer, importer, or distributor shall submit a written report to FDA of any correction or removal of a device initiated by such manufacturer or distributor if the correction or removal was initiated:

(1) To reduce a risk to health posed by the device; or

(2) To remedy a violation of the act caused by the device which may present a risk to health unless the information has already been provided as set forth in paragraph (f) of this section or the corrective or removal action is exempt from the reporting requirements under § 806.1(b).

(b) The manufacturer, importer, or distributor shall submit any report required by paragraph (a) of this section within 10-working days of initiating such correction or removal. The report shall be submitted to the appropriate FDA district office listed in § 5.115 of this chapter. A foreign manufacturer or owner or operator of devices must submit reports of corrective or removal actions.

(c) The manufacturer, importer, or distributor shall include the following information in the report:

(1) The seven digit registration number of the entity responsible for

submission of the report of corrective or removal action (if applicable), the month, day, and year that the report is made, and a sequence number (i.e., 001 for the first report, 002 for the second report, 003 etc.), and the report type designation ''C'' or ''R''. For example, the complete number for the first correction report submitted on June 1, 1997, will appear as follows for a firm with the registration number 1234567: 1234567–6/1/97–001–C. The second correction report number submitted by the same firm on July 1, 1997, would be 1234567–7/1/97–002–C etc. For removals, the number will appear as follows: 1234567–6/1/97–001–R and 1234567–7/1/97–002–R, etc. Firms that do not have a seven digit registration number may use seven zeros followed by the month, date, year, and sequence number (i.e. 0000000–6/1/97–001–C for corrections and 0000000–7/1/97–001–R for removals). Reports received without a seven digit registration number will be assigned a seven digit central file number by the district office reviewing the reports.

(2) The name, address, and telephone number of the manufacturer, importer, or distributor and the name, title, address, and telephone number of the manufacturer, importer, or distributor's representative responsible for conducting the device correction or removal.

(3) The brand name and the common name, classification name, or usual name of the device and the intended use of the device.

(4) Marketing status of the device, i.e., any applicable premarket notification number, premarket approval number, or indication that the device is a preamendments device, and the device listing number. A manufacturer, importer, or distributor that does not have an FDA establishment registration number shall indicate in the report whether it has ever registered with FDA.

(5) The model, catalog, or code number of the device and the manufacturing lot or serial number of the device or other identification number.

(6) The manufacturer's name, address, telephone number, and contact person if different from that of the person submitting the report.

(7) A description of the event(s) giving rise to the information reported and the corrective or removal actions that have been, and are expected to be taken.

(8) Any illness or injuries that have occurred with use of the device. If applicable, include the medical device report numbers.

(9) The total number of devices manufactured or distributed subject to the correction or removal and the number in the same batch, lot, or equivalent unit of production subject to the correction or removal.

(10) The date of manufacture or distribution and the device's expiration date or expected life.

(11) The names, addresses, and telephone numbers of all domestic and foreign consignees of the device and the dates and number of devices distributed to each such consignee.

(12) A copy of all communications regarding the correction or removal and the names and addresses of all recipients of the communications not provided in accordance with paragraph (c)(11) of this section.

(13) If any required information is not immediately available, a statement as to why it is not available and when it will be submitted.

(d) If, after submitting a report under this part, a manufacturer, distributor, or importer determines that the same correction or removal should be extended to additional lots or batches of the same device, the manufacturer, distributor, or importer shall within 10-working days of initiating the extension of the correction or removal, amend the report by submitting an amendment citing the original report number assigned according to paragraph (c)(1) of this section, all of the information required by paragraph (c)(2), and any information required by paragraphs (c)(3) through (c)(12) of this section that is different from the information submitted in the original report. The manufacturer, distributor, or importer shall also provide a statement in accordance with paragraph (c)(13) of this section for any required information that is not readily available.

(e) A report submitted by a manufacturer, distributor, or importer under this section (and any release by FDA of that report or information) does not necessarily reflect a conclusion by the manufacturer, distributor, importer, or FDA that the report or information constitutes an admission that the device caused or contributed to a death or serious injury. A manufacturer, distributor, or importer need not admit, and may deny, that the report or information submitted under this section constitutes an admission that the device caused or contributed to a death or serious injury.

(f) No report of a correction or removal is required under this part, if a report of the correction or removal is required and has been submitted under parts 803, 804, or 1004 of this chapter.

§ 806.20 Records of corrections and removals not required to be reported.

(a) Each device manufacturer, importer, or distributor who initiates a correction or removal of a device that is not required to be reported to FDA under § 806.10 shall keep a record of such correction or removal.

(b) Records of corrections and removals not required to be reported to FDA under § 806.10 shall contain the following information:

(1) The brand name, common or usual name, classification, name and product code if known, and the intended use of the device.

(2) The model, catalog, or code number of the device and the manufacturing lot or serial number of the device or other identification number.

(3) A description of the event(s) giving rise to the information reported and the corrective or removal action that has been, and is expected to be taken.

(4) Justification for not reporting the correction or removal action to FDA, which shall contain conclusions and any followups, and be reviewed and evaluated by a designated person.

(5) A copy of all communications regarding the correction or removal.

(c) The manufacturer, importer, or distributor shall retain all records required under this section for a period of 2 years beyond the expected life of the device, even if the manufacturer, importer, or distributor has ceased to manufacture, import, or distribute the device. Records required to be maintained under paragraph (b) of this section must be transferred to the new manufacturer, importer, or distributor of the device and maintained for the required period of time.

§ 806.30 FDA access to records.

Each device manufacturer, importer, or distributor required under this part to maintain records concerning corrections or removals and every person who is in charge or custody of such records shall, upon request of an officer or employee designated by FDA and under section 704(e) of the act, permit such officer or employee at all reasonable times to have access to, and to copy and verify, such records and reports.

§ 806.40 Public availability of reports.

(a) Any report submitted under this part is available for public disclosure in accordance with part 20 of this chapter.

(b) Before public disclosure of a report, FDA will delete from the report:

(1) Any information that constitutes trade secret or confidential commercial or financial information under § 20.61 of this chapter; and

(2) Any personnel, medical, or similar information, including the serial numbers of implanted devices, which would constitute a clearly unwarranted invasion of personal privacy under § 20.63 of this chapter or 5 U.S.C. 552(b)(6); provided, that except for the information under § 20.61 of this chapter or 5 U.S.C. 552(b)(4), FDA will disclose to a patient who requests a report all the information in the report concerning that patient.

Dated: May 9, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–13064 Filed 5–16–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

23 CFR Part 1327

[Docket No. 84–02; Notice 11]

RIN 2127–AG21

Procedures for Participating In and Receiving Data From the National Driver Register Problem Driver Pointer System

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Interim final rule; request for comments.

SUMMARY: This interim final rule amends the agency's National Driver Register (NDR) regulations to implement an amendment made by the Pilot Records Improvement Act of 1996. The amendment authorizes air carriers to receive information from the National Driver Register (NDR) regarding the motor vehicle driving records of individuals who are seeking employment with an air carrier as a pilot. This interim final rule establishes the procedures for those pilots to request, and for those air carriers to receive, NDR information.

DATES: This interim final rule becomes effective on May 19, 1997. Comments on this interim final rule are due no later than July 18, 1997.

ADDRESSES: Written comments should refer to the docket number and the number of this notice and be submitted (preferably in ten copies) to: Docket Section, National Highway Traffic Safety Administration, Room 5109, Nassif Building, 400 Seventh Street, SW., Washington, DC 20590. (Docket hours are from 9:30 a.m. to 4 p.m.)

FOR FURTHER INFORMATION CONTACT: Mr. William Holden, Chief, Traffic Records and Driver Register Division, NTS–32, National Highway Traffic Safety Administration, 400 Seventh Street SW., Washington, DC 20590; telephone (202) 366–4800 or Ms. Heidi L. Coleman, Assistant Chief Counsel for General Law, Office of Chief Counsel, NCC–30, National Highway Traffic Safety Administration, 400 Seventh Street SW., Washington, DC 20590; telephone (202) 366–1834.

SUPPLEMENTARY INFORMATION: The National Driver Register (NDR) is a central file of information on individuals whose licenses to operate a motor vehicle have been denied, revoked, suspended, or canceled, for cause, or who have been convicted of certain serious traffic-related violations, such as racing on the highways or driving while impaired by alcohol or other drugs.

As provided in the NDR Act of 1982, as amended, 49 U.S.C. 30301, *et seq.*, State chief driver licensing officials are authorized to request and receive information from the NDR for driver licensing and driver improvement purposes. When an individual applies for a driver's license, for example, these State officials are authorized to request and receive NDR information to determine whether the applicant's driver's license has been withdrawn for cause in any other State. Because the NDR is a nationwide index, chief driver licensing officials need to submit only a single inquiry to obtain this information.

State chief driver licensing officials are also authorized under the NDR Act to request NDR information on behalf of other authorized NDR users for transportation safety purposes. The NDR Act authorized the following transportation entities to receive NDR information for limited transportation safety purposes: The National Transportation Safety Board and the Federal Highway Administration for accident investigation purposes; employers and prospective employers of motor vehicle operators; the Federal Aviation Administration (FAA) regarding any individual who has received or applied for an airman's certificate; the Federal Railroad Administration (FRA) and employers or prospective employers of railroad locomotive operators; and the U. S. Coast Guard regarding any individual who holds or who has applied for a license, certificate of registry, or a merchant mariner's document. The Act also provided that individuals could learn whether information about themselves is on the NDR file and could receive any such information.

On October 9, 1996, the Pilot Records Improvement Act of 1996, Pub. L. 104–264, was enacted into law. Section 502 of that Act contained an amendment to the NDR Act of 1982, as amended, 49 U.S.C. 30305, authorizing air carriers to receive NDR information regarding individuals who are seeking employment with an air carrier as a pilot.

Procedures for Requesting and Receiving NDR Information

The procedures that air carriers would use to receive NDR information would be similar to those used by the employers of motor vehicle and railroad locomotive operators, the FAA, the FRA, and the U. S. Coast Guard in checking their applicants for employment or certification.

Air carriers may not initiate a request for NDR information. Rather, the individual seeking employment as a pilot must do so. To initiate a request, the individual must either complete, sign and submit a request for an NDR file search, or authorize the air carrier to request the NDR file search by completing and signing a written consent. The request or written consent must state that NDR records are being requested; state specifically who is authorized to receive the records; be dated and signed by the individual (the pilot); and specifically state that the authorization is valid for only one search of the NDR. It must also specifically state that the NDR identifies ''probable'' matches that require further inquiry for verification, that it is recommended (but not required) that the air carrier verify matches with the state of record, and state that individuals have the right to request NDR records regarding themselves to verify the accuracy of any information on the file pertaining to them.

The Pilot Records Improvement Act provides that an individual, about whom a request has been made, is entitled to receive written notice about the request for records and of the individual's right to receive a copy of any records provided to the prospective employer. Accordingly, the request or written consent that the individual completes must also include this notice.

The Pilot Records Improvement Act also provides that requests for NDR information are to be submitted through State chief driver licensing officials. Such requests may be submitted through the chief driver licensing official of any State that participates in the NDR's Problem Driver Pointer System (PDPS). Currently, 49 States (all States, except for the State of Oregon and the District of Columbia) participate