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FEDERAL LABOR RELATIONS AUTHORITY

5 CFR Ch. XIV

Amendment to Memorandum Describing the Authority and Assigned Responsibilities of the General Counsel of the Federal Labor Relations Authority

AGENCY: Federal Labor Relations Authority.

ACTION: Amendment to appendix to rules.

SUMMARY: This document amends Appendix B to 5 CFR Ch. XIV—Memorandum Describing the Authority and Assigned Responsibilities of the General Counsel of the Federal Labor Relations Authority. It clarifies the General Counsel's delegated authority to appoint acting Regional Directors when Regional Director positions become vacant.

EFFECTIVE DATE: This amendment was effective Wednesday, April 3, 1996.

FOR FURTHER INFORMATION CONTACT: Solly Thomas, Executive Director, Federal Labor Relations Authority, at (202) 482–6560.

SUPPLEMENTARY INFORMATION: The Federal Labor Relations Authority and the General Counsel of the Federal Labor Relations Authority were established by Reorganization Plan No. 2 of 1978, effective January 1, 1979. Since January 11, 1979, the provisions of the Federal Service Labor-Management Relations Statute (5 U.S.C. 7101–7135) (Statute) have governed the operations of the Authority and its General Counsel. The Authority separately stated and published in the Federal Register (44 FR 44777) on July 30, 1979, and republished on January 17, 1980 (45 FR 3255), a memorandum of the Authority describing the authority and assigned responsibilities of its General Counsel. The Authority subsequently published an amendment to the memorandum on June 23, 1983 (48 FR 28814). Pursuant to 5 U.S.C. 552(a)(1), the Authority hereby states and publishes in the Federal Register the following further amendment to the memorandum.

Accordingly, under the authority of 5 U.S.C. 552(a)(1), Section III, *Personnel*, of appendix B to 5 CFR Ch. XIV is revised to read as follows:

Appendix B to 5 CFR Ch. XIV—Memorandum Describing the Authority and Assigned Responsibilities of the General Counsel of the Federal Labor Relations Authority

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III. Personnel. Under 5 U.S.C. 7105(d), the Authority is authorized to appoint Regional Directors. In order better to ensure the effective exercise of the duties and responsibilities of the General Counsel described above, the General Counsel is delegated authority to recommend the appointment, transfer, demotion or discharge of any Regional Director. However, such actions may be taken only with the approval of the Authority. In the event of a vacant Regional Director position, the General Counsel may, without the approval of the Authority, detail personnel as acting Regional Director for a total period of up to 120 days commencing on the day the position becomes vacant. If the position remains vacant for more than 120 days, a detail must be approved by the Authority. Other details of personnel to act as Regional Director during periods when there is an incumbent in the position shall be accomplished by the General Counsel without the approval of the Authority. The General Counsel shall have authority to direct and supervise the Regional Directors. Under 5 U.S.C. 7104(f)(3), the General Counsel shall have direct authority over, and responsibility for all employees in the Office of the General Counsel and all personnel of the General Counsel in the field offices of the Authority. This includes full and final authority subject to applicable laws and rules, regulations and procedures of the Office of Personnel Management and the Authority over the selection, retention, transfer, promotion, demotion, discipline, discharge and in all other respects of such personnel except the detail in the event of a vacancy for a period in excess of 120 days, appointment, transfer, demotion or discharge of any Regional Director. Further, the establishment, transfer, or elimination of any Regional Office or non-Regional Office duty location may be accomplished only with the approval of the Authority. The Authority will provide such administrative support functions, including personnel management, financial management and procurement functions, through the Office of Administration of the Authority as are required by the General Counsel to carry out the General Counsel's statutory and prescribed functions.

Dated: April 4, 1996.

For the Authority.

Solly Thomas,

Executive Director, Federal Labor Relations Authority.

[FR Doc. 96–9018 Filed 4–10–96; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 803 and 807

[Docket No. 91N–0295]

RIN 0910–AA09

Medical Devices; Medical Device User Facility and Manufacturer Reporting, Certification and Registration; Office of Management and Budget Approval; Extension of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; notification of approval of information collection requirements.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the Office of Management and Budget (OMB) has approved the collection of information requirements in the final rule on medical device user facility and manufacturer reporting, certification and registration. In addition, FDA is extending to July 31, 1996, the effective date of the final rule in response to requests and in order to allow sufficient time for user facilities and manufacturers to implement procedures to comply with the final rule. The final rule was published in the Federal Register of December 11, 1995 (60 FR 63578).

EFFECTIVE DATE: July 31, 1996.

FOR FURTHER INFORMATION CONTACT: Earl W. Robinson, Center for Devices and Radiological Health (HFZ–530), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–2735.

SUPPLEMENTARY INFORMATION: In the Federal Register of December 11, 1995

(60 FR 63578), FDA published a final rule (21 CFR parts 803 and 807) requiring medical device user facilities and manufacturers to report adverse events related to medical devices under a uniform reporting system. In the preamble to the final rule (60 FR 63578 at 63596), FDA announced that the collection of information requirements contained in the final rule had been submitted to OMB for approval under the Paperwork Reduction Act of 1995 (Pub. L. 104–13). The agency also requested public comment on the information collection requirements by January 10, 1996. The agency further stated that these collection of information requirements would not become effective until FDA obtained OMB approval of them, and that FDA would publish in the Federal Register a notice of OMB's decision to approve, modify, or disapprove them.

FDA received 26 comments regarding the information collection requirements. Comments were reviewed by both FDA and OMB. On February 23, 1996, OMB sent FDA a notice of action stating that the collection of information requirements are approved for use through February 28, 1999, under OMB control number 0910–0059. Persons are not required to respond to a collection of information unless it displays a currently valid OMB control number.

In response to comments to the information collection requirements, FDA is changing the effective date of the final rule and providing certain clarifications and guidance regarding requirements of the final rule.

1. Several comments requested that the date of the final rule be extended to allow manufacturers and user facilities additional time to set up procedures to implement the new requirements. These comments stated that the effective date of the final rule, April 11, 1996, would not allow them enough time after approval of the forms to set up reporting procedures, databases, and train personnel. FDA agrees that reporting entities need additional time to set up reporting procedures. FDA, on the basis of these comments on the information collection, is extending that comment period to July 31, 1996, without further notice and comment procedures.

The Administrative Procedure Act and FDA regulations provide that the agency may issue a regulation without notice and comment procedures when the agency for good cause finds (and incorporates the finding and a brief statement of reasons thereof in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest (5 U.S.C. 553(b)(8); 21 CFR 10.40(e)(1)). FDA finds that there is good cause for dispensing with notice and comment procedures to extend the effective date of the final rule because such procedures are impracticable, unnecessary, and contrary to the public interest.

First, notice and comment rulemaking on the extension of the effective date is impracticable. FDA was unable to prepare and issue notice of the extension of the effective date until April 11, 1996. Because the final rule's effective date is April 11, 1996, there is not enough time for FDA to solicit a new round of notice and comment before the effective date. Although the final rule informing reporting entities of the new requirements was published on December 11, 1995, reporters have not known what forms would be required until the issuance of this notice. Without the forms, reporting entities have heretofore been unable to set up their reporting procedures and databases or train personnel. Adequate procedures and training will ensure that reporters generate reports that contain meaningful information that will allow FDA efficiently evaluate adverse events. FDA believes that reporting entities need until July 31, 1996, to set up adequate procedures to implement the new reporting requirements.

Second, engaging in notice and comment rulemaking is unnecessary. The public has already had two separate opportunities to comment on the effective date; the first in response to the request in the tentative final rule for comments, and the second in response to the request in the request in the final rule for comments relating to the information collection requirements. All of the comments FDA has received are in favor of extending the effective date to allow reporters adequate time to set up procedures to implement the new regulations. FDA does not believe another round of notice and comment is necessary on an issue that has already received two rounds of public comment.

Third, notice and comment rulemaking is contrary to the public interest. Extending the effective date of the rule without notice and comment allows reporters immediate certainty as to the timeframes that they have to set up procedures to implement the new reporting requirements. If FDA did not provide a definite effective date, reporters may bear additional expense and hardship in setting up inefficient interim procedures in order to be ready to report on a certain date, when that date may ultimately be extended. Moreover, because reports generated under interim procedures would be processed without adequate time to implement proper training and procedures, such reports may be of poor quality that would preclude both reporters and FDA from obtaining information to evaluate adverse events effectively. Certain knowledge of the date the regulation will be effective will allow reporters to know the exact timeframe that will allow them to implement procedures to effectively evaluate and submit reports.

For all the reasons stated above, FDA concludes, under 5 U.S.C. 553(b)(B) and 21 CFR 10.40(e)(1), there is good cause for extending the effective date of the final rule without notice and comment procedures. Consistent with its own procedural regulations, however, FDA is providing an opportunity for comment on its decision to delay the effective date of the final regulation until July 31, 1996.

2. Several comments stated that FDA should reconsider requiring a baseline report (FDA Form 3417) for each model number because reporters would have to submit many separate baseline reports for virtually identical devices that have option and accessory packages that are identified by a model number variation, such as a prefix or suffix.

Section 803.55 requires that a manufacturer shall submit a baseline report for a device when the device *model* is first reported under § 803.50. The regulation does not require a baseline report for every model number variation. FDA does not believe that the regulation requires a separate baseline report for every model number variation, if the variation could not affect the device's safety or effectiveness. If a manufacturer groups model numbers, it should list each model number variation on the baseline report that is included (e.g., basic model number 900; model number variations, R900, 900C, 900D, and R900C). FDA will match the variations of the model number reported on form 3500A to the list of model numbers provided on the baseline reports.

3. Comments requested further clarification on the definition of ''device family'' (§ 803.3(e)) that is used to identify similar groups of devices on the manufacturer baseline report. FDA classified and revised § 803.3(e) to define ''device family'' as devices that have the same basic design and performance characteristics related to safety and effectiveness, intended use and function, and device classification and product code. Devices that differ only in minor ways not related to safety or effectiveness can be considered to be in the same device family. Factors such as brand name and common name of the device and whether the devices were

introduced into commercial distribution under the same 510(k) or premarket approval application, may be considered in grouping products into device families.As part of implementation of the final regulation, FDA will provide further information, guidance and examples.

4. Comments objected to the requirement on the annual certification form for manufacturers (FDA Form 3381) that the firm certify not only the number of reports submitted during the 12-month period for which the certification is submitted, but also that this number constitutes all the reportable events for which the firm is responsible during that period.

FDA responded to similar comments in the preamble to the final rule (60 FR 63578 at 63591). For the reasons stated therein, FDA still believes that it is necessary and within FDA's statutory authority to require that manufacturers certify that they have submitted all reportable events to FDA. FDA believes that certification is an important means of increasing the effectiveness of the Medical Device Reporting (MDR) system. FDA, however, realizes that there may be situations, hopefully rare, when a manufacturer, for example, did not ''become aware,'' as defined in 803.1(c) (21 CFR 803.1(c)), of information reasonably suggesting a reportable event has occurred, and therefore could not have submitted a report, or there may be an occasional instance of miscounting the number of reports. FDA, therefore, has determined that it is appropriate for manufacturers to state that they are certifying the statements on FDA Form 3381 to the best of their knowledge. FDA has revised the form accordingly. It now states:

I certify that, to the best of my knowledge, the firms listed in item 3. above either submitted the MDR indicated above during the stated reporting period and that this number represents the submissions for all appropriately reportable MDR events or that the firm listed above did not receive any MDR reportable events during this time period. I also certify that, to the best of my knowledge, the statements and information presented in this submission are truthful and accurate.

5. Comments objected to the requirement that annual updates to baseline reports be submitted on the anniversary date of the initial baseline report. The comments noted that, for companies who submit baseline reports for numerous devices, they would have to keep track of many different submission dates for update baseline reports. The comments suggested that manufacturers be allowed to submit all baseline updates on a single date, e.g., the date on which annual certification is required.

FDA agrees with the comments and believes that it is an acceptable interpretation of the regulation to allow an annual update on the date on which the annual certification is due.

Section 803.55(a) requires that a manufacturer shall submit its first baseline report ''for a device when the device model is first reported under § 803.50'' (i.e., an individual adverse event report). Section 803.55(b) requires that each baseline report shall be updated annually, on the anniversary month of the initial submission. The time a manufacturer is required to submit the update of their baseline report under § 803.55(b), is therefore contingent upon the time a manufacturer is considered to have ''first reported'' an adverse event for a particular device model.

FDA believes that a manufacturer could interpret § 803.55(a) to mean that the first baseline report update could be submitted on the date a firm is required to submit its next certification. Accordingly, the firm could thereafter submit its annual baseline update report on the date of the firm's next annual certification. For example, if a manufacturer submits its first adverse event baseline report for a device on March 1, 1996, it could submit its first baseline report on the date of its next certification report, November 1, 1996. Thereafter, it would submit its update baseline report on November 1, 1997.

FDA intends to make a guidance document on the final rule available during April 1996, and will announce it's availability in the Federal Register. FDA also intends to hold a nationwide teleconference by satellite on May 7, 1996, during which FDA officials will speak on the final rule and be available to answer questions. When more details are available, FDA will publicize these initiatives through the Facts-on-Demand system administered by FDA's Division of Small Manufacturers Assistance, Center for Devices and Radiological Health, and the electronic docket. To access this information through Facts-on-Demand dial 1–800–899–0381 (outside MD) or 1–301–827–0111 (inside MD) and enter document number 799.

Dated: March 30, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–8970 Filed 4–5–96; 3:26 pm]

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 811

[Docket No. FR–3985–C–02]

RIN 2502–AG64

Office of the Assistant Secretary for Housing-Federal Housing Commissioner: Regulatory Reinvention; Tax Exemption of Obligations of Public Housing Agencies and Related Amendments; Final Rule; Correction

AGENCY: Office of the Assistant Secretary for Housing-Federal Housing Commissioner, HUD.

ACTION: Final rule; correction.

SUMMARY: On April 1, 1996 (61 FR 14456), HUD published a final rule streamlining its regulations governing the tax exemption of obligations of public housing agencies. The preamble to the April 1, 1996 final rule stated that HUD was removing subpart B of 24 CFR part 811. However, the rule's regulatory text did not contain an amendatory instruction removing this subpart. The purpose of this document is to correct the April 1, 1996 final rule by removing 24 CFR part 811, subpart B.

FOR FURTHER INFORMATION CONTACT: James Mitchell, Director, Financial Services Division, Department of Housing and Urban Development, 470 L'Enfant Plaza East, room 3120, Washington, DC 20024, telephone number (202) 708–7450, ext. 125 (this is not a toll-free number). For hearing- and speech-impaired persons, this number may be accessed via TTY by calling the Federal Information Relay Service at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: On March 4, 1995, President Clinton issued a memorandum to all Federal departments and agencies regarding regulatory reinvention. In response to this memorandum, HUD conducted a page-by-page review of its regulations to determine which could be eliminated, consolidated, or otherwise improved. As part of this review, HUD examined its regulations at 24 CFR part 811, which govern the tax exemption of obligations of public housing agencies. HUD determined that 24 CFR part 811 could be improved and streamlined by eliminating unnecessary provisions.

On April 1, 1996 (61 FR 14456), HUD published a final rule which streamlined part 811 by eliminating provisions that were redundant of statutes or otherwise unnecessary. The program described in subpart B of part 811, concerning the purchase of GNMA