

support of its assertion, FDA is denying the request for a hearing on this point because a hearing will not be granted on the basis of mere allegations or denials or general descriptions of positions and contentions (21 CFR 12.24(b)(2)).

(5) Public Citizen asserts that by FDA failing to comply with § 170.22, FDA did not comply with § 170.20 (21 CFR 170.20), which states that “the Commissioner will be guided by the principles and procedures for establishing the safety of food additives stated in current publications of the National Academy of Sciences National Research Council.”

Section 170.22 pertains to safety factors to be applied to animal experimentation data in determining whether a proposed use of a food additive is safe. As discussed previously in item 4, no animal studies were necessary nor were any conducted to demonstrate that the use of 7.5 MeV x-rays is safe for treating food. Because the provisions of § 170.22 do not apply to the agency’s review of FAP 3M4745, Public Citizen’s assertion that FDA did not comply with § 170.20 because it did not comply with § 170.22 is without merit. Therefore, this objection is not a basis for a hearing because there is no genuine and substantial issue of fact for resolution (§ 12.24(b)(1)).

(6) Public Citizen asserts that FDA did not comply with 21 U.S.C. 348(c)(3)(A), which states that “No such regulation shall issue if a fair evaluation of the data before the Secretary—(A) fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe: *Provided*, That no additive shall be deemed to be safe if it is found to induce cancer when ingested by man.” Nor has FDA complied with § 170.3(i), which defines “safe” as “there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use.”

Public Citizen has not provided any evidence to support these allegations or that contradicts or challenges the agency’s safety determination. The agency finds that this objection is merely a general description of Public Citizen’s position, and that it does not raise a factual issue for resolution at a hearing. Therefore, FDA is denying the requests for a hearing on this point because there is no genuine and substantial issue of fact for resolution at a hearing, and a hearing will not be granted on the basis of mere allegations or denials or general descriptions of positions and contentions (§ 12.24(b)(1) and (b)(2)).

V. Summary and Conclusions

Section 409 of the act requires that a food additive be shown to be safe prior to marketing. Under § 170.3(i), a food additive is “safe” if there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use. In the final rule approving the use of 7.5 MeV x-rays for treating food, FDA concluded, based on its evaluation of the data submitted in the petition and other relevant material, that the use of 7.5 MeV x-rays proposed in the petition for treating food is safe under the conditions set forth in the regulation codified at § 179.26. The petitioner has the burden to demonstrate the safety of the additive in order to gain FDA approval. Once FDA makes a finding of safety, the burden shifts to an objector, who must come forward with evidence that calls into question FDA’s conclusion (*American Cyanamid Co. v. FDA*, 606 F.2d 1307, 1314–1315 (D.C. Cir. 1979)).

None of the objections received contained evidence to support a genuine and substantial issue of fact. Nor has any objector established that the agency overlooked significant information in reaching its conclusion. Therefore, the agency has determined that the objections that requested a hearing do not raise any substantial issue of fact that would justify an evidentiary hearing (§ 12.24(b)). Accordingly, FDA is not making any changes in response to the objections and is denying the requests for a hearing.

Dated: March 27, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 803, 814, 820, 821, 822, 874, 886, 1002, 1005, and 1020

[Docket No. 2007N-0104]

Medical Devices; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending certain medical device regulations to correct typographical errors and to

ensure accuracy and clarity in the agency’s regulations.

EFFECTIVE DATE: April 9, 2007.

FOR FURTHER INFORMATION CONTACT: Philip Desjardins, Center for Devices and Radiological Health (HFZ-215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 240-276-2343.

SUPPLEMENTARY INFORMATION: FDA is amending its regulations in parts 803, 814, 820, 821, 822, 874, 886, 1002, 1005, and 1020 to correct typographical errors, and update addresses, telephone numbers, and wording to ensure accuracy and clarity in the agencies medical device regulations.

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because these errors are nonsubstantive.

I. Highlights of the Final Rule

FDA is making changes to correct typographical and other minor errors in certain device regulations in parts 803, 814, 820, 821, 822, 874, 886, 1002, 1005, and 1020 (21 CFR 803, 814, 820, 821, 822, 874, 886, 1002, 1005, and 1020).

1. FDA is revising § 803.11 and replacing “301-443-8818” with “240-276-3151.”

2. FDA is revising § 803.11 and replacing “<http://www.fda.gov/cdrh/mdr/mdr-forms.html>” with “<http://www.fda.gov/medwatch/getforms.htm>.”

3. FDA is revising § 803.21(a) and replacing “301-443-8818” with “240-276-3151.”

4. FDA is revising § 803.21(a) and replacing “<http://www.fda.gov/cdrh/mdr/373.html>” with “<http://www.fda.gov/cdrh/mdr/mdr-forms.html>.”

5. FDA is revising § 814.20(g) and replacing “FDA has issued a PMA guidance document to assist the applicant in the arrangement and content of a PMA. This guidance document is available on the Internet at <http://www.fda.gov/cdrh/dsma/pmaman/front.html>. This guidance document is also available upon request from the Center for Devices and Radiological Health, Division of Small Manufacturers Assistance (HFZ-220), 1350 Piccard Dr., Rockville, MD 20850, FAX 301-443-8818” with “Additional information on FDA policies and procedures, as well as links to PMA guidance documents, is available on the Internet at <http://www.fda.gov/cdrh/devadvice/pma/>.”

6. FDA is revising § 820.1(e) and replacing “Division of Small

Manufacturers Assistance (HFZ-220), 1350 Piccard Dr., Rockville, MD 20850, U.S.A., telephone 1-800-638-2041 or 1-301-443-6597, FAX 301-443-8818" with "Division of Small Manufacturers, International and Consumer Assistance (HFZ-220), 1350 Piccard Dr., Rockville, MD 20850, U.S.A., telephone 1-800-638-2041 or 240-276-3150, FAX 240-276-3151."

7. FDA is revising § 821.2(c) and removing the words "and Surveillance."

8. FDA is revising § 822.7(b) and replacing "(www.fda.gov/cdrh/resolvingdisputes), and from the CDRH Facts-on-Demand system (800-899-0381 or 301-827-0111)" with "(<http://www.fda.gov/cdrh/ombudsman/dispute.html>)."

9. FDA is revising § 822.15 and replacing "You may obtain guidance regarding dispute resolution procedures from the Center for Devices and Radiological Health's (CDRH) Web site (www.fda.gov/cdrh/resolvingdisputes/ombudsman.html) and from the CDRH Facts-on-Demand system (800-899-0381 or 301-827-0111, document number 1121)" with "You may obtain guidance regarding dispute resolution procedures from the Center for Devices and Radiological Health's (CDRH's) Web site (www.fda.gov/cdrh/ombudsman/)."

10. FDA is revising § 822.22(b) and replacing "You may obtain guidance documents that discuss these mechanisms from the CDRH Web site and from the CDRH Facts-on-Demand System (800-899-0381 or 301-827-0111)" with "You may obtain guidance documents that discuss these mechanisms from the Center for Devices and Radiological Health's (CDRH's) Web site."

11. FDA is revising § 874.4420 and replacing "tonsil suction tub" with "tonsil suction tube."

12. FDA is revising § 874.4420 and replacing "ear suction tub" with "ear suction tube."

13. FDA is revising the section title in § 886.1090 and replacing "Haidlinger" with "Haidinger."

14. FDA is revising § 886.1090(a) and replacing "Haidlinger" with "Haidinger."

15. FDA is revising § 1002.7 and replacing "shall be addressed to the Center for Devices and Radiological Health, Electronic Product Reports, Office of Compliance (HFZ-307), 2098 Gaither Rd., Rockville, MD 20850" with "shall be addressed to the Center for Devices and Radiological Health, ATTN: Electronic Product Reports, Radiological Health Document Control (HFZ-309), Office of Communication, Education, and Radiation Programs, 9200 Corporate Blvd, Rockville, MD 20850.

16. FDA is revising § 1002.10 and replacing "Center for Devices and Radiological Health, Electronic Product Reports, Office of Compliance (HFZ-307), 2098 Gaither Rd., Rockville, MD 20850" with "Center for Devices and Radiological Health, ATTN: Electronic Product Reports, Radiological Health Document Control (HFZ-309), Office of Communication, Education, and Radiation Programs, 9200 Corporate Blvd, Rockville, MD 20850."

17. FDA is revising § 1002.20(b) and replacing "Director, Center for Devices and Radiological Health, 5600 Fishers Lane, Rockville, MD 20857" with "Center for Devices and Radiological Health, ATTN: Accidental Radiation Occurrence Reports (HFZ-240), Office of Communication, Education, and Radiation Programs, 9200 Corporate Boulevard, Rockville, MD 20850."

18. FDA is revising § 1002.50(c)(3) and replacing "Office of Compliance (HFZ-307)" with "Office of Communication, Education, and Radiation Programs (HFZ-240)."

19. FDA is revising § 1005.11 and replacing "5600 Fishers Lane, Rockville, MD 20857" with "(HFZ-204), 9200 Corporate Blvd., Rockville, MD 20857."

20. FDA is revising § 1005.25(b) and adding "(HFZ-240)."

21. FDA is revising § 1020.30(c) and replacing "Office of Compliance and Surveillance" with "Office of Communication, Education, and Radiation Programs."

II. Environmental Impact

The agency has determined under 21 CFR 25.30(i) that this final rule is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement was required.

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is not a significant regulatory action under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory

options that would minimize any significant impact of a rule on small entities. Because this rule corrects only typographical and nonsubstantive errors in existing regulations and does not change in any way how devices are regulated, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is \$122 million, using the most current (2005) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

IV. Paperwork Reduction Act of 1995

FDA has determined that this final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

V. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VI. The Technical Amendments

This rule updates and corrects existing regulations to ensure accuracy and clarity. This administrative action is limited to correcting typographical errors; updating changes in addresses, web site locations, and telephone numbers; and clarifying regulation terminology. It makes no changes in substantive requirements.

For the effective date of this final rule see **EFFECTIVE DATE**. Because this final

rule is an administrative action, FDA has determined that it has no substantive impact on the public. It imposes no costs, and merely makes technical administrative changes in the Code of Federal Regulations (CFR) for the convenience of the public. FDA, therefore, for good cause, finds under 5 U.S.C. 553(b)(3)(B) and (d)(3) that notice and public comment are unnecessary.

List of Subjects

21 CFR Part 803

Imports, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 814

Administrative practice and procedure, Confidential business information, Medical devices, Medical research, Reporting and recordkeeping requirements.

21 CFR Part 820

Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 821

Imports, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 822

Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 874

Medical devices.

21 CFR Part 886

Medical devices, Ophthalmic goods and services.

21 CFR Part 1002

Electronic products, Radiation protection, Reporting and recordkeeping requirements.

21 CFR Part 1005

Administrative practice and procedure, Electronic products, Imports, Radiation protection, Surety bonds.

21 CFR Part 1020

Electronic products, Medical devices, Radiation protection, Reporting and recordkeeping requirements, Television, X-rays.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 803, 814, 820, 821, 822, 874, 886, 1002, 1005, and 1020 are amended as follows:

PART 803—MEDICAL DEVICE REPORTING

■ 1. The authority section for part 803 continues to read as follows:

Authority: 21 U.S.C. 352, 360, 360i, 360j, 371, 374.

■ 2. Section 803.11 is revised to read as follows:

§ 803.11 What form should I use to submit reports of individual adverse events and where do I obtain these forms?

If you are a user facility, importer, or manufacturer, you must submit all reports of individual adverse events on FDA MEDWATCH Form 3500A or in an electronic equivalent as approved under § 803.14. You may obtain this form and all other forms referenced in this section from any of the following:

(a) The Consolidated Forms and Publications Office, Beltsville Service Center, 6351 Ammendale Rd., Landover, MD 20705;

(b) FDA, MEDWATCH (HF-2), 5600 Fishers Lane, Rockville, MD 20857, 301-827-7240;

(c) Division of Small Manufacturers, International, and Consumer Assistance, Office of Communication, Education, and Radiation Programs, Center for Devices and Radiological Health (CDRH) (HFZ-220), 1350 Piccard Dr. Rockville, MD 20850, by e-mail: DSMICA@CDRH.FDA.GOV, or FAX: 240-276-3151;

(d) On the Internet at <http://www.fda.gov/medwatch/getforms.htm>.

■ 3. In § 803.21, paragraph (a) is revised to read as follows:

§ 803.21 Where can I find the reporting codes for adverse events that I use with medical device reports?

(a) The MEDWATCH Medical Device Reporting Code Instruction Manual contains adverse event codes for use with FDA Form 3500A. You may obtain the coding manual from CDRH's Web site at <http://www.fda.gov/cdrh/mdr/mdr-forms.html>; and from the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, 1350 Piccard Dr., Rockville, MD 20850, FAX: 240-276-3151, or e-mail to DSMICA@CDRH.FDA.GOV.

* * * * *

PART 814—PREMARKET APPROVAL OF MEDICAL DEVICES

■ 4. The authority section for part 814 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 353, 360, 360c-360j, 371, 372, 373, 374, 375, 379, 379e, 381.

■ 5. In § 814.20, paragraph (g) is revised to read as follows:

§ 814.20 Application.

* * * * *

(g) Additional information on FDA policies and procedures, as well as links

to PMA guidance documents, is available on the Internet at <http://www.fda.gov/cdrh/devadvice/pma/>.

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PART 820—QUALITY SYSTEMS REGULATION

■ 6. The authority section for part 820 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, 383.

■ 7. In § 820.1, paragraph (e)(1) is revised to read as follows:

§ 820.1 Scope.

* * * * *

(e) *Exemptions or variances.* (1) Any person who wishes to petition for an exemption or variance from any device quality system requirement is subject to the requirements of section 520(f)(2) of the act. Petitions for an exemption or variance shall be submitted according to the procedures set forth in § 10.30 of this chapter, the FDA's administrative procedures. Guidance is available from the Center for Devices and Radiological Health, Division of Small Manufacturers, International and Consumer Assistance (HFZ-220), 1350 Piccard Dr., Rockville, MD 20850, U.S.A., telephone 1-800-638-2041 or 240-276-3150, FAX 240-276-3151.

* * * * *

PART 821—MEDICAL DEVICE TRACKING REQUIREMENTS

■ 8. The authority section for part 821 continues to read as follows:

Authority: 21 U.S.C. 331, 351, 352, 360, 360e, 360h, 360i, 371, 374.

■ 9. In § 821.2, paragraph (c) is revised to read as follows:

§ 821.2 Exemptions and variances.

* * * * *

(c) An exemption or variance is not effective until the Director, Office of Compliance, CDRH, approves the request under § 10.30(e)(2)(i) of this chapter.

PART 822—POSTMARKET SURVEILLANCE

■ 10. The authority section for part 822 continues to read as follows:

Authority: 21 U.S.C. 331, 352, 360i, 360l, 371, 374.

■ 11. In § 822.7, paragraph (b) is revised to read as follows:

§ 822.7 What should I do if I do not agree that postmarket surveillance is appropriate?

* * * * *

(b) You may obtain guidance documents that discuss these mechanisms from the Center for Devices and Radiological Health's (CDRH's) Web site (<http://www.fda.gov/cdrh/ombudsman/dispute.html>).

■ 12. Section 822.15 is revised to read as follows:

§ 822.15 How long must I conduct postmarket surveillance of my device?

The length of postmarket surveillance will depend on the postmarket surveillance question identified in our order. We may order prospective surveillance for a period up to 36 months; longer periods require your agreement. If we believe that a prospective period of greater than 36 months is necessary to address the surveillance question, and you do not agree, we will use the Medical Devices Dispute Resolution Panel to resolve the matter. You may obtain guidance regarding dispute resolution procedures from the Center for Devices and Radiological Health's (CDRH's) Web site (www.fda.gov/cdrh/ombudsman/). The 36-month period refers to the surveillance period, not the length of time from the issuance of the order.

■ 13. In § 822.22, paragraph (b) is revised to read as follows:

§ 822.22 What recourse do I have if I do not agree with your decision?

* * * * *

(b) You may obtain guidance documents that discuss these mechanisms from the Center for Devices and Radiological Health's (CDRH's) Web site.

PART 874—EAR, NOSE, AND THROAT DEVICES

■ 14. The authority section for part 874 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 15. In § 874.4420, paragraph (a) is revised to read as follows:

§ 874.4420 Ear, nose, and throat manual surgical instrument.

(a) *Identification.* An ear, nose, and throat manual surgical instrument is one of a variety of devices intended for use in surgical procedures to examine or treat the bronchus, esophagus, trachea, larynx, pharynx, nasal and paranasal sinus, or ear. This generic type of device includes the esophageal dilator; tracheal bistour (a long, narrow surgical knife); tracheal dilator; tracheal hook; laryngeal injection set; laryngeal knife; laryngeal saw; laryngeal trocar; laryngectomy tube; adenoid curette; adenotome; metal tongue depressor; mouth gag; oral

screw; salpingeal curette; tonsillectomy; tonsil guillotine; tonsil screw; tonsil snare; tonsil suction tube; tonsil suturing hook; antom retractor; ethmoid curette; frontal sinus-rasp; nasal curette; nasal rasp; nasal rongeur; nasal saw; nasal scissors; nasal snare; sinus irrigator; sinus trephine; ear curette; ear excavator; ear rasp; ear scissor, ear snare; ear spoon; ear suction tube; malleous ripper; mastoid gauge; microsurgical ear chisel; myringotomy tube inserter; ossici holding clamp; sacculotomy tack inserter; vein press; wire ear loop; microrule; mirror; mobilizer; ear, nose, and throat punch; ear, nose and throat knife; and ear, nose, and throat trocar.

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PART 886—OPHTHALMIC DEVICES

■ 16. The authority section for part 886 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 17. In § 886.1090, the section title and paragraph (a) are revised to read as follows:

§ 886.1090 Haidinger brush.

(a) *Identification.* A Haidinger brush is an AC-powered device that provides two conical brushlike images with apexes touching which are viewed by the patient through a Nicol prism and intended to evaluate visual function. It may include a component for measuring macular integrity.

* * * * *

PART 1002—RECORDS AND REPORTS

■ 18. The authority section for part 1002 continues to read as follows:

Authority: 21 U.S.C. 352, 360, 360i, 360j, 360hh–360ss, 371, 374.

■ 19. In § 1002.7, the introductory text is revised to read as follows:

§ 1002.7 Submission of data and reports.

All submissions such as reports, test data, product descriptions, and other information required by this part, or voluntarily submitted to the Director, Center for Devices and Radiological Health, shall be filed with the number of copies as prescribed by the Director, Center for Devices and Radiological Health, and shall be signed by the person making the submission. The submissions required by this part shall be addressed to the Center for Devices and Radiological Health, ATTN: Electronic Product Reports, Radiological Health Document Control (HFZ–309), Office of Communication, Education,

and Radiation Programs, 9200 Corporate Blvd., Rockville, MD 20850.

* * * * *

■ 20. In § 1002.10, the introductory text is revised to read as follows:

§ 1002.10 Product reports.

Every manufacturer of a product or component requiring a product report as set forth in table 1 of § 1002.1 shall submit a product report to the Center for Devices and Radiological Health, ATTN: Electronic Product Reports, Radiological Health Document Control (HFZ–309), Office of Communication, Education, and Radiation Programs, 9200 Corporate Blvd., Rockville, MD 20850, prior to the introduction of such product into commerce. The report shall be distinctly marked “Radiation Safety Product Report of (name of manufacturer)” and shall:

* * * * *

■ 21. In § 1002.20, paragraph (b) is revised to read as follows:

§ 1002.20 Reporting of accidental radiation occurrences.

* * * * *

(b) Such reports shall be addressed to the Center for Devices and Radiological Health, ATTN: Accidental Radiation Occurrence Reports (HFZ–240), Office of Communication, Education, and Radiation Programs, 9200 Corporate Blvd., Rockville, MD 20850, and the reports and their envelopes shall be distinctly marked “Report on 1002.20” and shall contain all of the following information where known to the manufacturer:

- (1) The nature of the accidental radiation occurrence;
- (2) The location at which the accidental radiation occurrence occurred;
- (3) The manufacturer, type, and model number of the electronic product or products involved;
- (4) The circumstances surrounding the accidental radiation occurrence, including causes;
- (5) The number of persons involved, adversely affected, or exposed during the accidental radiation occurrence, the nature and magnitude of their exposure and/or injuries and, if requested by the Director, Center for Devices and Radiological Health, the names of the persons involved;
- (6) The actions, if any, which may have been taken by the manufacturer, to control, correct, or eliminate the causes and to prevent reoccurrence; and

(7) Any other pertinent information with respect to the accidental radiation occurrence.

* * * * *

■ 22. In § 1002.50, paragraph (c)(3) is revised to read as follows:

§ 1002.50 Special exemptions.

* * * * *

(c) * * *

(3) Such conditions as are deemed necessary to protect the public health and safety. Copies of exemptions shall be available upon request from the Center for Devices and Radiological Health, Office of Communication, Education, and Radiation Programs (HFZ-240), 9200 Corporate Blvd., Rockville, MD 20850.

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PART 1005—IMPORTATION OF ELECTRONIC PRODUCTS

■ 23. The authority section for part 1005 continues to read as follows:

Authority: 42 U.S.C. 263d, 263h.

■ 24. Section 1005.11 is revised to read as follows:

§ 1005.11 Payment for samples.

The Department of Health and Human Services will pay for all import samples of electronic products rendered unsalable as a result of testing, or will pay the reasonable costs of repackaging such samples for sale, if the samples are found to be in compliance with the requirements of the Radiation Control for Health and Safety Act of 1968. Billing for reimbursement shall be made by the owner or consignee to the Center for Devices and Radiological Health (HFZ-204), 9200 Corporate Blvd., Rockville, MD 20857. Payment for samples will not be made if the sample is found to be in violation of the Act, even though subsequently brought into compliance pursuant to terms specified in a notice of permission issued under § 1005.22.

■ 25. In § 1005.25, paragraph (b) is revised to read as follows:

§ 1005.25 Service of process on manufacturers.

* * * * *

(b) A manufacturer designating an agent must address the designation to the Center for Devices and Radiological Health (HFZ-240), 9200 Corporate Blvd., Rockville, MD 20850. It must be in writing and dated; all signatures must be in ink. The designation must be made in the legal form required to make it valid and binding on the manufacturer under the laws, corporate bylaws, or other requirements governing the

making of the designation by the manufacturer at the place and time where it is made, and the persons or person signing the designation shall certify that it is so made. The designation must disclose the manufacturer's full legal name and the name(s) under which the manufacturer conducts the business, if applicable, the principal place of business, and mailing address. If any of the products of the manufacturer do not bear his legal name, the designation must identify the marks, trade names, or other designations of origin which these products bear. The designation must provide that it will remain in effect until withdrawn or replaced by the manufacturer and shall bear a declaration of acceptance duly signed by the designated agent. The full legal name and mailing address of the agent must be stated. Until rejected by the Secretary, designations are binding on the manufacturer even when not in compliance with all the requirements of this section. The designated agent may not assign performance of his function under the designation to another.

* * * * *

PART 1020—PERFORMANCE STANDARDS FOR IONIZING RADIATION EMITTING PRODUCTS

■ 26. The authority section for part 1020 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 360e-360j, 360gg-360ss, 371, 381.

■ 27. In § 1020.30, paragraph (c) is revised to read as follows:

§ 1020.30 Diagnostic x-ray systems and their major components.

* * * * *

(c) *Manufacturers' responsibility.* Manufacturers of products subject to §§ 1020.30 through 1020.33 shall certify that each of their products meet all applicable requirements when installed into a diagnostic x-ray system according to instructions. This certification shall be made under the format specified in § 1010.2 of this chapter. Manufacturers may certify a combination of two or more components if they obtain prior authorization in writing from the Director of the Office of Communication, Education, and Radiation Programs of the Center for Devices and Radiological Health. Manufacturers shall not be held responsible for noncompliance of their products if that noncompliance is due solely to the improper installation or assembly of that product by another person; however, manufacturers are responsible for providing assembly instructions adequate to assure

compliance of their components with the applicable provisions of §§ 1020.30 through 1020.33.

* * * * *

Dated: March 28, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7-6290 Filed 4-6-07; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1300 and 1313

[Docket No. DEA-292I]

RIN 1117-AB06

Implementation of the Combat Methamphetamine Epidemic Act of 2005; Notice of Transfers Following Importation or Exportation

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Interim Final Rule with Request for Comment.

SUMMARY: This regulation implements section 716 of the Combat Methamphetamine Epidemic Act (CMEA) of 2005 (21 U.S.C. 971 as amended), which was enacted on March 9, 2006. DEA is amending its regulations to require additional reporting for import, export, and international transactions involving all List I and List II chemicals. This rule implements section 716 of the CMEA which extends current reporting requirements for importations, exportations, and international transactions involving List I and List II chemicals.

DATES: This rule is effective May 9, 2007. Written comments must be postmarked, and electronic comments must be sent, on or before May 9, 2007.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-292" on all written and electronic correspondence. Written comments being sent via regular mail should be sent to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative/ODL. Written comments sent via express mail should be sent to DEA Headquarters, Attention: DEA Federal Register Representative/ODL, 2401 Jefferson-Davis Highway, Alexandria, VA 22301. Comments may be directly sent to DEA electronically by sending an electronic message to dea.diversion.policy@usdoj.gov.