2009, and include the ingredients added as of the date of submission. Section 904(c) of the act also requires submission of information whenever additives, or the quantities of additives, are changed.

FDA issued guidance documents on both (1) Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments (November 12, 2009, 74 FR 58298) and (2) Listing of Ingredients in Tobacco Products (December 1, 2009, 74 FR 62795) to assist persons making such submissions to FDA under the Tobacco Control Act. While electronic submission of registration and product listing information and ingredient listing information are not required, FDA is strongly encouraging electronic submission to facilitate efficiency and timeliness of data management and collection. To that end, FDA designed the eSubmitter application to streamline the data entry process for registration and product listing and for ingredient listing. This tool allows for importation of large quantities of structured data, attachments of files (e.g., in portable document format (PDFs) and certain media files), and automatic acknowledgement of FDA's receipt of submissions. FDA also developed paper forms (FDA Form 3742—Registration and Listing for Owners and Operators of Domestic Tobacco Product Establishments and FDA Form 3743—Listing of Ingredients in Tobacco Products) as an alternative submission tool. Both the eSubmitter application and the paper forms can be accessed at *http://www.fda.gov/tobacco*.

On September 1, 2009 (74 FR 45219), FDA published notice in the **Federal Register** announcing that a proposed collection of information had been submitted to OMB for emergency processing under the Paperwork Reduction Act of 1995. On September 15, 2009 (74 FR 47257), FDA published a notice correcting the length of the comment period, keeping it open until October 1, 2009. On October 13, 2009 (74 FR 52495), FDA published a notice reopening the comment period until October 26, 2009. Based on comments indicating that the burden estimates were too low, FDA has adjusted its original burden estimates. FDA has adjusted its burden estimate for registration and product listing for owners and operators of domestic establishments under section 905 of the act from 0.75 hours per response to 3.75 hours per response. FDA has adjusted its burden estimate for listing of ingredients under section 904 of the act from 0.75 hours per response to 3.0 hours per response. FDA also decreased the number of respondents for listing of ingredients under section 904 from 100,000 to 11,000 in response to comments that this estimate was too high. FDA also added the activity of applying for a Dun and Bradstreet D-U-N-S number to the burden of this information collection for those who chose to use eSubmitter.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Respondents	Hours per Response	Total Hours
Registration and Product Listing for Owners and Operators of Domestic Establishments	100,000	1	100,000	3.75	375,000
Listing of Ingredients	11,000	1	11,000	3.0	33,000
Obtaining a Dun and Bradstreet D-U-N-S Number	1,550	1	1,550	0.5	775
Total	112,550		112,550		408,775

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: February 4, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–3031 Filed 2–17–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0434]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Humanitarian Device Exemption Holders, Institutional Review Boards, Clinical Investigators, and Food and Drug Administration Staff: Humanitarian Device Exemption Regulation: Questions and Answers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by March 22, 2010.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–NEW and title Guidance for Humanitarian Device Exemption Holders, Institutional

Review Boards, Clinical Investigators, and Food and Drug Administration Staff: Humanitarian Device Exemption Regulation: Questions and Answers; Availability. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., P150–400B, Rockville, MD 20850, 301–796–3793.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Humanitarian Device Exemption Holders, Institutional Review Boards , Clinical Investigators, and Food and Drug Administration Staff: Humanitarian Device Exemption Regulation: Questions and Answers (OMB Control Number 0910–NEW)—Extension

Title III of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110–85) amended chapter V of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 351 *et seq.*) by inserting section 515A, Pediatric Uses of Devices (21 U.S.C. 360e–1).

This new provision requires that new applications under section 520(m) of the act (21 U.S.C. 360j(m)) include both a description of any pediatric subpopulation that suffer from: (1) A disease or condition that the device is intended to treat, diagnose, or cure and (2) the number of affected pediatric patients.

Title III of FDAAA also amended section 520(m) of the act as follows:

Section 520(m)(6)(A)(ii) provides that the Secretary of Health and Human Services will assign an annual distribution number (ADN) for devices indicated for use in a pediatric population or in a pediatric subpopulation. The ADN shall be based on the following information in a humanitarian device exemption (HDE) application: (1) The number of individuals affected by the disease or condition that such device is intended to treat, diagnose, or cure and of that number; (2) the number of individuals likely to use the device and (3) the number of devices reasonably necessary to treat such individuals.

Section 520(m)(6)(A)(iii) provides that an HDE holder immediately notify the agency if the number of devices distributed during any calendar year exceeds the ADN.

Section 520(m)(6)(C) provides that an HDE holder may petition to modify the ADN if additional information on the number of individuals affected by the disease or condition arises.

In the **Federal Register** of August 5, 2008 (73 FR 45460), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA had previously published a 30-day notice on September 30, 2009 (74 FR 50214) and is republishing this 30-day notice to provide a more descriptive response to the comments received in response to the August 5, 2008, notice.

FDA received 7 letters in response to the August 5, 2008, notice. Six of the seven comments were substantive, each containing several comments regarding many of the 66 questions contained in the guidance. The comments and the agency's responses are discussed in the following paragraphs:

(Comment) Several of the comments sought clarification regarding when the Annual Distribution Number (ADN) reporting requirement applied.

(Response) A paragraph was added to clarify that the ADN relates only to those devices that are on the market through the HDE process for a disease or condition that occurs in pediatric patients or in a pediatric subpopulation. The response to Question 27 was augmented to include the phrase "independent Institutional Review Board (IRB)" to clarify that not all IRBs are internal bodies within a hospital or clinic.

(Comment) Question 31 was augmented to describe the different reporting requirements for manufacturers and for user facilities.

(Response) Manufacturers must submit reports to FDA and the "IRB of record" whenever a humanitarian use device (HUD) may have caused or contributed to a death or serious injury, or has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur (§§ 803.50 and 814.126(a) (21 CFR 803.50 and 814.126(a))). User facilities must submit reports to FDA, the "IRB of record" and the manufacturer whenever a HUD may have caused or contributed to a death. They must also submit reports to FDA and the "IRB of record" if the manufacturer is unknown, whenever a HUD may have caused or contributed to a serious injury (§§ 803.30 and 814.126(a)).

(Comment) Some of the comments related to the placement of information in the draft guidance.

(Response) In Question 40, the statement: "If a HUD is being investigated in an Investigational Device Exemption, (IDE) Study for a different indication, does it impact the number of allowable patients under the HDE" was redesignated as question 35 and moved from the "IRB Section" of the guidance and placed in the section, "After FDA Approves an HDE" because it did not pertain directly to IRBs.

(Comment) Changes were made to the section, "The Role of Institutional Review Boards (IRBs)," question 37 specifically, in order to clarify the distinction between the terms "use," "HUD," and "investigational use/clinical investigation" of a HUD.

(Response) Specifically, FDA clarified that the term "use" in the guidance, when unmodified, refers to the use of a HUD according to its approved labeling and indication(s). If a HUD is being used in a clinical investigation (i.e., collection of safety and effectiveness data), whether for its HDE-approved indications or for a different indication, then this document refers to "investigational use" or "clinical investigation" of the HUD. Finally in addition to adding clarifying information, a decision tree was also added to the guidance for ease of reference for IRBs.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Section of the Federal Food, Drug, and Cosmetic Act	No. of Respondents	Annual Frequency per Response	Total Annual Respondents	Hours per Response	Total Hours
515A(a)(2)	5	1	5	100	500
520(m)(6)(A)(ii)	3	1	3	50	150

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

Section of the Federal Food, Drug, and Cosmetic Act	No. of Respondents	Annual Frequency per Response	Total Annual Respondents	Hours per Response	Total Hours
520(m)(6)(A)(iii)	1	1	1	100	100
520(m)(6)(C)	5	1	5	100	500
Total					1,250

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA based these estimates on the number of original HDE applications that the Center for Devices and Radiological Health (CDRH) received for the period October 1, 2004, through September 30, 2007. During that time, CDRH received 16 original HDE applications or about 5 per year.

FDA estimates that for each year, CDRH will receive five HDE applications and that three of these applications will be indicated for pediatric use. One HDE holder will notify the agency that the number of devices distributed in the year has exceeded the ADN and five HDE holders will petition to have the ADN modified due to additional information on the number of individuals affected by the disease of condition.

The draft guidance refers also to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR part 803 have been approved under OMB control number 0910–0437; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, subparts A, B, and C, have been approved under OMB control number 0910–0231; the collection of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910–0130; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; the collections of information in 21 CFR part 814, subpart H, have been approved under OMB control number 0910–0332; and the collection of information requirements in 21 CFR 10.30 have been approved under OMB control number 0910–0183.

Dated: February 4, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–3030 Filed 2–17–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0512]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Antimicrobial Animal Drug Distribution Reports Under Section 105 of the Animal Drug User Fee Amendments of 2008

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by March 22, 2010.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910—NEW and title "Antimicrobial Animal Drug Distribution Reports Under Section 105 of the Animal Drug User Fee Amendments of 2008." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Antimicrobial Animal Drug Distribution Reports Under Section 105 of the Animal Drug User Fee Amendments of 2008—(OMB Control Number 0910–NEW)—Extension

Section 105 of the Animal Drug User Fee Amendments of 2008 (ADUFA) amended section 512 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b) to require that the sponsor of each new animal drug that contains an antimicrobial agent submit an annual report to FDA on the amount of each antimicrobial active ingredient in the drug that is sold or distributed for use in food-producing animals, including information on any distributor-labeled product. The legislation was enacted to address the problem of antimicrobial resistance, and to help ensure that FDA has the necessary information to examine safety concerns related to the use of antibiotics in food-producing animals (154 Congressional Record H7534).

Each report must specify: (1) The amount of each antimicrobial active ingredient by container size, strength, and dosage form; (2) quantities distributed domestically and quantities exported; and (3) a listing of the target animals, indications, and production classes that are specified on the approved label of the product.

The first report must be submitted not later than March 31, 2010. The report must cover the period of the preceding calendar year and include separate information for each month of the calendar year. The reports required under section 105 of ADUFA are required to be separate from periodic drug experience reports that are required under § 514.80(b)(4) (21 CFR § 514.80(b)(4) (OMB Control No. 0910–0284).

In the **Federal Register** of October 26, 2009 (74FR 55046), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received comments from two organizations. Both commenters supported the information collection and stated that the data to be collected would be useful in addressing