

Health guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. Persons unable to download an electronic copy of “Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Device” may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1400057 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 collections of information in 21 CFR part 814 have been approved under OMB control number 0910–0231. 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 812 have been approved under OMB control number 0910–0078. The collections of

information in 21 CFR part 814, subpart H have been approved under OMB control number 0910–0332. The collections of information in the guidance document “Guidance for HDE Holders, Institutional Review Boards (IRBs), Clinical Investigators, and FDA Staff—Humanitarian Device Exemption (HDE) Regulation: Questions and Answers” have been approved under OMB control number 0910–0661.

Dated: July 5, 2016.
Leslie Kux,
Associate Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2009–N–0221; FDA–2012–N–0559; FDA–2015–N–3287; FDA–2015–N–3815; FDA–2007–D–0429; FDA–2012–N–0447; FDA–2011–D–0597; FDA–2011–D–0164; FDA–2013–N–0013; FDA–2011–N–0146; FDA–2014–N–1533; FDA–2011–N–0921; FDA–2015–N–2163]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North 10A63, 11601 Landsdown St., North Bethesda, MD 20852, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Food Labeling: Notification Procedures for Statements on Dietary Supplements	0910–0331	6/30/2019
PHS Guideline on Infectious Disease Issues in Xenotransplantation	0910–0456	6/30/2019
MDUFMA Small Business Qualification Certification	0910–0508	6/30/2019
Electronic Submission of Medical Device Registration and Listing	0910–0625	6/30/2019
Guidance for Industry on Q & A Regarding Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement & Nonprescription Drug Consumer Protection Act	0910–0641	6/30/2019
Antimicrobial Animal Drug Distribution Reports and Recordkeeping	0910–0659	6/30/2019
Guidance for Industry on Oversight of Clinical Investigations: A Risk-Based Approach to Monitoring	0910–0733	6/30/2019
Guidance for Industry on Safety Labeling Changes; Implementation of the Federal Food, Drug, and Cosmetic Act	0910–0734	6/30/2019
Accreditation of Third Party Certification Bodies to Conduct Food Safety Audits and Issue Certifications	0910–0750	6/30/2019
Sanitary Transportation of Human and Animal Food	0910–0773	6/30/2019
National Panel of Tobacco Consumer Studies	0910–0815	6/30/2019
Standards for the Growing, Harvesting, Packaging, and Holding of Produce for Human Consumption	0910–0816	6/30/2019
Hearing, Aging, and Direct-to-Consumer Television Advertisements	0910–0818	6/30/2019

Dated: July 6, 2016.
Leslie Kux,
Associate Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0242]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Current Good Manufacturing Practice for Positron Emission Tomography Drugs

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 August 10, 2016.

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 emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0667 and title "Current Good Manufacturing Practice for Positron Emission Tomography Drugs." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North 10A63, 11601 Landsdown St., North Bethesda, MD 20852, PRASStaff@fda.hhs.gov.

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.

Current Good Manufacturing Practice for Positron Emission Tomography Drugs OMB Control Number 0910-0667—Extension

Positron emission tomography is a medical imaging modality involving the use of a unique type of radiopharmaceutical drug product. FDA's Current Good Manufacturing Practice (CGMP) regulations at 21 CFR part 212 are intended to ensure that positron emission tomography (PET) drug products meet the requirements of

the Federal Food, Drug, and Cosmetic Act (the FD&C Act) regarding safety, identity, strength, quality, and purity. The CGMP requirements for PET drugs are issued under the provisions of the Food and Drug Administration Modernization Act of 1997 (the Modernization Act). These CGMP requirements are designed to take into account the unique characteristics of PET drugs, including their short half-lives, and the fact that most PET drugs are produced at locations that are very close to the patients to whom the drugs are administered.

The CGMP regulations are intended to ensure that approved PET drugs meet the requirements of the FD&C Act as to safety, identity, strength, quality, and purity. The regulations address the following matters: Personnel and resources; quality assurance; facilities and equipment; control of components, in-process materials, and finished products; production and process controls; laboratory controls; acceptance criteria; labeling and packaging controls; distribution controls; complaint handling; and recordkeeping.

The CGMP regulations establish several recordkeeping requirements and a third-party disclosure requirement for the production of PET drugs. In making our estimates of the time spent in complying with these information collection requirements, we relied on informal communications we have had with PET producers, visits by our staff to PET facilities, and our familiarity with both PET and general pharmaceutical manufacturing practices.

In the **Federal Register** of December 29, 2015 (80 FR 81332), FDA published a 60-day notice requesting public comment on the proposed collection of information and the estimated annual burden for recordkeeping and third party disclosure. In response to the notice, FDA received several comments. The comments raised a number of issues that are discussed as follows.

(Comment 1) The comment disagreed with FDA's estimate that 129 PET drug production facilities are required to comply with part 212. Based on its records, the comment said that approximately 150 facilities are subject to the PET CGMP requirements.

(Response) We have revised the burden estimates to account for 150 PET drug production facilities.

(Comment 2) The comment disagreed with FDA's statement in section I of the December 29, 2015, **Federal Register** notice, "Investigational and Research PET Drugs." The comment said that PET facilities devote resources to comply

with USP 32 Chapter 823, and that FDA should estimate the recordkeeping burden under USP 32 Chapter 823.

(Response) FDA agrees with the comment that facilities incur a burden to comply with USP 32 Chapter 823. However, compliance with USP provisions is beyond the scope of this information collection, which only pertains to the requirements under part 212.

(Comment 3) The comment said FDA "averages" the burden across different categories of respondents and responses, and that this approach results in lower burden estimates. For example, the comment said that most recordkeeping will continue to be with a paper-based system and not an electronic system, and that the costs are different for each system. In addition, there are differences between the costs incurred by commercial and academic facilities.

(Response) All commercial PET drug facilities are currently utilizing electronic records for recordkeeping as well as paper-based records. Commercial PET drug manufacturers comprise approximately 90 percent of the manufacturing sites. Many academic PET facilities still use paper-based records. However, academic PET sites produce fewer batches for clinical use compared to commercial sites, and have fewer records. Sufficient resources and personnel are needed to perform the PET drug production activities, and academic PET drug sites limited in personnel and resources do bear more of the regulatory burden. After a firm's recordkeeping process is established, the burdens are generally the same for entering records into an electronic system or a paper-based system. We question whether it is worthwhile to prepare separate estimates for commercial versus academic sites because academic sites are a small percentage of the total. Also, providing an average estimate is consistent with PRA requirements and, based on our calculations, the number of academic sites that apply for drug applications represents a small percentage.

(Comment 4) The comment questioned FDA's methodology for determining the burden estimates, especially in table 2 where the actual burden may be underestimated "by a factor of 10 to 100."

(Response) In estimating the time to comply with these information collection requirements, we relied on