I. Background

This guidance describes FDA's policy regarding the regulation of medical x-ray imaging equipment that is subject to the FD&C Act and FDA's regulations that apply to medical devices and electronic products. In this guidance, FDA is seeking to harmonize performance standards prescribed pursuant to section 534 of Subchapter C (Electronic Product Radiation Control (EPRC)) of the FD&C Act (21 U.S.C. 360(kk)) with International Electrotechnical Commission (IEC) standards, where appropriate, to help to ensure streamlined regulatory review of submissions for these products. The guidance also provides recommendations to industry on how to comply with the applicable requirements. FDA has determined that industry conformance to certain IEC standards would provide, at a minimum, the same level of protection of the public health and safety from electronic radiation as certain EPRC regulatory standards. In addition, due to the recent publication of a proposed rule (84 FR 12147) on April 1, 2019, that would, if finalized, eliminate the reporting requirements for x-ray imaging devices, FDA determined that the proposed policy outlined in section 4 of the draft guidance, which stated that x-ray imaging devices that conform to IEC standards would be considered to have met the EPRC reporting requirements, should be removed from the guidance. This decision was made to avoid the confusion inherent in establishing an interim procedure that would shortly be superseded by the final rule. However, as stated in section V. of the guidance, FDA believes that submission of a declaration of conformity to the appropriate standards, and model identification as required by 21 CFR 1002.10(a) and (b), in a product report, would be sufficient to meet the requirements of a product report under 21 CFR 1002.10, thus reducing duplication.

FDA considered comments received on the draft guidance that appeared in the **Federal Register** of August 3, 2016 (81 FR 51201). FDA revised the guidance as appropriate in response to the comments.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Medical X-Ray Imaging Devices Conformance with IEC Standards.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Persons unable to download an electronic copy of ''Medical X-Ray Imaging Devices Conformance with IEC Standards'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1400014 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

In the **Federal Register** of August 3, 2016 (81 FR 51201), we requested comments on the revision of OMB control number 0910–0025, ''Reporting and Recordkeeping for Electronic Products—General Requirements,'' to adjust the annual reporting burden consistent with the policy in the draft guidance pertaining to reports. However, because this final guidance does not include this policy pertaining to reports (see the Background section), we have determined that the guidance no longer necessitates revisions to OMB control number 0910–0025.

This guidance refers to previously approved collections of information. 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 the following FDA regulations have been approved by OMB as listed in the following table:

21 CFR part	Topic	OMB control No.
807, subpart E	Premarket Notification	0910–0120
800, 801, and 809	Medical Device Labeling Regulations	0910–0485
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation	0910–0073
1002 through 1050	Reporting and Recordkeeping for Electronic Products—General Requirements	0910–0025

Dated: May 2, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–09405 Filed 5–7–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1344]

Policy Clarification for Certain Fluoroscopic Equipment Requirements; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled ''Policy Clarification for Certain Fluoroscopic Equipment Requirements.'' This guidance document intends to clarify FDA's interpretation of certain aspects of the performance standard requirements in FDA's regulations for fluoroscopic equipment.

DATES: The announcement of the guidance is published in the **Federal Register** on May 8, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2014–D–1344 for ''Policy Clarification for Certain Fluoroscopic Equipment Requirements.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Policy Clarification for Certain Fluoroscopic Equipment Requirements'' to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Donald Miller, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4318, Silver Spring, MD 20993–0002, 301–796–3299.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance document intends to clarify FDA's interpretation of certain aspects of the performance standard requirements in §§ 1020.30 and 1020.32 (21 CFR 1020.30 and 1020.32) for fluoroscopic equipment. Specifically, it clarifies FDA's interpretation of fluoroscopic irradiation time (§ 1020.30(b)), the permissible duration of the activation of the x-ray tube in the fluoroscopic mode (§ 1020.32(c)), and on inclusion of an emergency fluoroscopy mode in fluoroscopes.

FDA considered comments received on the draft guidance that appeared in the **Federal Register** of September 25, 2014 (79 FR 57559). FDA revised the guidance as appropriate in response to the comments.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Policy Clarification for Certain Fluoroscopic Equipment Requirements.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* This guidance document is also available at *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Policy Clarification for Certain Fluoroscopic Equipment Requirements'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document 1806 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. 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 the following FDA regulations have been approved by OMB as listed in the following table:

21 CFR part	Topic	OMB control No.
807, subpart E	Premarket Notification	0910–0120
1020	Reporting and Recordkeeping for Electronic Products—General Requirements	0910–0025

Dated: May 2, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–09406 Filed 5–7–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3138]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Experimental Study of an Accelerated Approval Disclosure

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 (PRA).

DATES: Fax written comments on the collection of information by June 7, 2019.

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 *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–NEW and title ''Experimental Study of an Accelerated Approval Disclosure.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@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.

Experimental Study of an Accelerated Approval Disclosure

OMB Control Number 0910–NEW

I. Background

Section 1701(a)(4) of the Public Health Service Act (PHS Act) (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 393(d)(2)(C)) authorizes FDA to conduct research relating to drugs and other FDA-regulated products in carrying out the provisions of the FD&C Act.

The mission of the Office of Prescription Drug Promotion (OPDP) is to protect the public health by helping to ensure that prescription drug information is truthful, balanced, and accurately communicated so that patients and healthcare providers can make informed decisions about treatment options. The OPDP's research program supports this mission by providing scientific evidence to help ensure that our policies related to prescription drug promotion will have the greatest benefit to public health. Toward that end, we have consistently conducted research to evaluate the aspects of prescription drug promotion that we believe are most central to our mission, focusing in particular on three main topic areas: advertising features, including content and format; target populations; and research quality. Through the evaluation of advertising features, we assess how elements such as graphics, format, and disease and product characteristics impact the communication and understanding of prescription drug risks and benefits; focusing on target populations allows us to evaluate how understanding of prescription drug risks and benefits may vary as a function of audience; and our focus on research quality aims at maximizing the quality of research data through analytical methodology development and investigation of sampling and response issues. This study falls under the topic of advertising features (content and format).

Pursuant to section 506(c) of the FD&C Act (21 U.S.C. 356(c)) and 21 CFR part 314, subpart H (or 21 CFR part 601, subpart E for biological products), FDA may grant accelerated approval to a drug product under section 505(c) of the FD&C Act (21 U.S.C. 355(c)) or a biological product under section 351(a) of the PHS Act (42 U.S.C 262(a)). This pathway enables faster approval of prescription drugs intended to treat serious or life-threatening illnesses. Accelerated approval may be based on a determination that a drug product has an effect on a surrogate endpoint (for example, a blood test result) that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit (*i.e.,* an intermediate clinical endpoint). In approving a drug under the accelerated approval pathway, the severity, rarity, or prevalence of a condition, and the availability or lack of alternative treatments, are taken into account.

The accelerated approval pathway is limited to certain products intended to treat serious or life-threatening illnesses as there can be ''[u]ncertainty about whether clinical benefit will be verified and the possibility of undiscovered risks'' (FDA 2014 guidance for industry entitled ''Expedited Programs for Serious Conditions—Drugs and Biologics,'' available at *https://www.fda.gov/files/drugs/published/Expedited-Programs-for-Serious-Conditions-Drugs-and-Biologics.pdf*). Sponsors are generally required to conduct post approval studies to verify and describe the predicted clinical benefit, but those confirmatory studies are not complete at the time that the accelerated approval is granted (Ref. 1). In the event that the required post approval confirmatory studies fail to verify and describe the predicted effect or clinical benefit, a drug's approval can be withdrawn using expedited procedures.

Under FDA's regulations governing physician labeling for prescription drugs, the INDICATIONS AND USAGE section of the FDA-approved prescribing information (PI) for a drug approved under accelerated approval must include a succinct description of the limitations of usefulness of the drug and any uncertainty about anticipated clinical benefits, with reference to the clinical studies section for a discussion of the available evidence (21 CFR