

## References

EPA. 2009. Endocrine Disruptor Screening Program Test Guidelines. OPPTS 890.1300: Estrogen Receptor Transcriptional Activation (Human Cell Line (HeLa-9903)). Washington, DC: U.S. Environmental Protection Agency. Available: <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0576-0006>.

ICCVAM. 2011. ICCVAM Test Method Evaluation Report: The LUMI-CELL® ER (BG1Luc ER TA) Test Method: An *In Vitro* Assay for Identifying Human Estrogen Receptor Agonist and Antagonist Activity of Chemicals. Research Triangle Park, NC: National Institute of Environmental Health Sciences. Available: <http://iccvam.niehs.nih.gov/methods/endocrine/ERTA-TMER.htm>.

ICCVAM. 2006. Addendum to ICCVAM Evaluation of *In Vitro* Test Methods for Detecting Potential Endocrine Disruptors. Research Triangle Park, NC: National Institute of Environmental Health Sciences. Available: [http://iccvam.niehs.nih.gov/docs/endo\\_docs/EDAddendFinal.pdf](http://iccvam.niehs.nih.gov/docs/endo_docs/EDAddendFinal.pdf).

ICCVAM. 2003a. ICCVAM Evaluation of *In Vitro* Test Methods For Detecting Potential Endocrine Disruptors: Estrogen Receptor and Androgen Receptor Binding and Transcriptional Activation Assays. NIH Publication No. 03-4503. Research Triangle Park, NC: National Institute of Environmental Health Sciences. Available: [http://iccvam.niehs.nih.gov/methods/endocrine/end\\_TMER.htm](http://iccvam.niehs.nih.gov/methods/endocrine/end_TMER.htm).

ICCVAM. 2002a. Background Review Document. Current Status of Test Methods for Detecting Endocrine Disruptors: *In Vitro* Estrogen Receptor Transcriptional Activation Assays. NIH Publication No. 03-4505. Research Triangle Park, NC: National Institute of Environmental Health Sciences. Available: [http://iccvam.niehs.nih.gov/methods/endocrine/end\\_bckgnd.htm#ERTA](http://iccvam.niehs.nih.gov/methods/endocrine/end_bckgnd.htm#ERTA).

ICCVAM. 2002b. Background Review Document. Current Status of Test Methods for Detecting Endocrine Disruptors: *In Vitro* Androgen Receptor Binding Assays. NIH Publication No. 03-4506. Research Triangle Park, NC: National Institute of Environmental Health Sciences. Available: [http://iccvam.niehs.nih.gov/methods/endocrine/end\\_bckgnd.htm#ARBnd](http://iccvam.niehs.nih.gov/methods/endocrine/end_bckgnd.htm#ARBnd).

ICCVAM. 2002c. Background Review Document: Current Status of Test Methods for Detecting Endocrine Disruptors: *In Vitro* Estrogen Receptor Binding Assays. NIH Publication No. 03-4504. Research Triangle Park, NC: National Institute of Environmental Health Sciences. Available: [http://iccvam.niehs.nih.gov/methods/endocrine/end\\_bckgnd.htm#ERBnd](http://iccvam.niehs.nih.gov/methods/endocrine/end_bckgnd.htm#ERBnd).

ICCVAM. 2002d. Background Review Document. Current Status of Test Methods for Detecting Endocrine Disruptors: *In Vitro* Androgen Receptor Transcriptional Activation Assays. NIH Publication No. 03-4507. Research Triangle Park, NC: National Institute of Environmental Health Sciences. Available: [http://iccvam.niehs.nih.gov/methods/endocrine/end\\_bckgnd.htm#ARTA](http://iccvam.niehs.nih.gov/methods/endocrine/end_bckgnd.htm#ARTA).

ICCVAM. 2002e. Expert Panel Evaluation of the Validation Status of *In Vitro* Test Methods for Detecting Endocrine Disruptors: Estrogen Receptor and Androgen Receptor

Binding and Transcriptional Activation Assays. Expert Panel Final Report. Research Triangle Park, NC: National Institute of Environmental Health Sciences. Available: [http://iccvam.niehs.nih.gov/methods/endocrine/end\\_EPrt.htm](http://iccvam.niehs.nih.gov/methods/endocrine/end_EPrt.htm).

OECD. 2009. Test No 455: The Stably Transfected Human Estrogen Receptor-alpha Transcriptional Activation Assay for Detection of Estrogenic Agonist-Activity of Chemicals. In: OECD Guidelines for the Testing of Chemicals, Section 4: Health Effects. Paris: OECD Publishing. Available: [http://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals-section-4-health-effects\\_20745788](http://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals-section-4-health-effects_20745788).

Rogers JM, Denison MS. 2000. Recombinant cell bioassays for endocrine disruptors: Development of a stably transfected human ovarian cell line for the detection of estrogenic and anti-estrogenic chemicals. *In Vitro Mol Toxicol* 13(1):67-82.

Dated: February 7, 2012.

**John R. Bucher,**

*Associate Director, National Toxicology Program.*

[FR Doc. 2012-3437 Filed 2-13-12; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier CMS-10421]

### Agency Information Collection Activities: Proposed Collection; Comment Request

#### Correction

In notice document 2012-2821 appearing on pages 6123-6124 in the issue of February 7, 2012, make the following correction:

On page 6124, in the first column, in the last line, "April 9, 2012" should read "April 3, 2012".

[FR Doc. C1-2012-2821 Filed 2-13-12; 8:45 am]

**BILLING CODE 1505-01-D**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0110]

### Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device Reporting; Manufacturer, Importer, User Facility, and Distributor Reporting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an

opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on medical device reporting (MDR); manufacturer, importer, user facility, and distributor reporting.

**DATES:** Submit either electronic or written comments on the collection of information by April 16, 2012.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, [Daniel.Gittleson@fda.hhs.gov](mailto:Daniel.Gittleson@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and

assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Medical Device Reporting: Manufacturer, Importer, User Facility, and Distributor Reporting—21 CFR Part 803 (OMB Control Number 0910-0437)—Extension**

Section 519(a)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360i(a)(1)) requires every manufacturer or importer to report “whenever the manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices: (A) May have caused or contributed to a death or serious injury, or (B) has malfunctioned and that such device or a similar device marketed by

the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.”

Section 519(b)(1)(A) of the FD&C Act requires “whenever a device user facility receives or otherwise becomes aware of information that reasonably suggests that a device has or may have caused or contributed to the death or serious illness, of a patient of the facility, the facility shall, as soon as practicable but not later than 10 working days after becoming aware of the information, report the information to the Secretary and, if the identity of the manufacturer is known, to the manufacturer of the device.”

Section 519(b)(1)(B) of the FD&C Act requires “whenever a device user facility receives or otherwise becomes aware of: (i) Information that reasonably suggests that a device has or may have caused or contributed to the serious illness of, or serious injury to, a patient of the facility \* \* \*, shall, as soon as practicable but not later than 10

working days after becoming aware of the information, report the information to the manufacturer of the device or to the Secretary if the identity of the manufacturer is not known.”

Complete, accurate, and timely adverse event information is necessary for the identification of emerging device problems. Information from these reports will be used to evaluate risks associated with medical devices which will enable FDA to take appropriate regulatory measures in protection of the public health under section 519 of the FD&C Act. Thus FDA is requesting approval for these information collection requirements which are being implemented under part 803 (21 CFR part 803).

Respondents to this collection of information are businesses or other for-profit and nonprofit organizations including user facilities, manufacturers, and importers of medical devices.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

21 CFR section/ form FDA No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
803.19 .....	57	4	228	3	684
803.30 and .32 .....	393	2	777	1	777
803.33 Form FDA 3419 .....	393	1	393	1	393
803.40 and .42 .....	73	37	2,682	1	2,682
803.50 and .52 .....	1,601	104	166,271	1	166,271
803.56 .....	1,200	63	76,186	1	76,186
Total .....					246,993

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
803.17 .....	220	1	220	10	2,200
803.18 (c) & (d) .....	30,000	1	30,000	1.5	45,000
Total .....					47,200

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Part 803 requires user facilities to report to the device manufacturer and to FDA in case of a death, incidents where a medical device caused or contributed to a death or serious injury. Additionally, user facilities are required to annually submit the number and summary of adverse events reported during the calendar year, using Form FDA 3419. Manufacturers of medical devices are required to report to FDA when they become aware of information indicating that one of their devices may have

caused or contributed to death or serious injury or has malfunctioned in such a way that should the malfunction recur it would be likely to cause or contribute to a death or serious injury. Device importers report deaths and serious injuries to the manufacturers and FDA. Importers report malfunctions only to the manufacturers, unless they are unknown, then the reports are sent to FDA.

The number of respondents for each CFR section in table 1 of this document

is based upon the number of respondents entered into FDA’s internal databases. FDA estimates, based on its experience and interaction with the medical device community, that all reporting CFR sections are expected to take 1 hour to complete, with the exception of § 803.19. Section 803.19 is expected to take approximately 3 hours to complete, but is only required for reporting the summarized data quarterly to FDA. By summarizing events, the total time used to report for this section

is reduced because the respondents do not submit a full report for each event they report in a quarterly summary report.

The Agency believes that the majority of manufacturers, user facilities, and importers have already established written procedures to document complaints and information to meet the MDR requirements as part of their internal quality control system. There are an estimated 30,000 medical device distributors. Although they do not submit MDR reports, they must maintain records of complaints, under § 803.18(d).

The Agency has estimated that on average 220 user facilities, importers, and manufacturers would annually be required to establish new procedures, or revise existing procedures, in order to comply with this provision.

Therefore, FDA estimates the one-time burden to respondents for establishing or revising procedures under § 803.17 to be 2,200 hours (220 respondents x 10 hours). For those entities, a one-time burden of 10 hours is estimated for establishing written MDR procedures. The remaining manufacturers, user facilities, and importers, not required to revise their written procedures to comply with this provision, are excluded from the burden because the recordkeeping activities needed to comply with this provision are considered "usual and customary" under 5 CFR 1320.3(b)(2).

Under § 803.18, 30,000 respondents represent distributors, importers, and other respondents to this information collection. FDA estimates that it should take them approximately 1.5 hours to complete the recordkeeping requirement for this section. Total hours for this section equal 45,000 hours.

Dated: February 9, 2012.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2012-3344 Filed 2-13-12; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-D-0081]

#### Draft Guidance on Investigational New Drug Applications for Positron Emission Tomography Drugs; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "Investigational New Drug Applications for Positron Emission Tomography (PET) Drugs." The draft guidance is intended to assist manufacturers of PET drugs in submitting investigational new drug applications (INDs).

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by May 14, 2012.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, Rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:**

Kyong (Kaye) Kang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2352, Silver Spring, MD 20993, 301-796-2050.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

FDA is announcing the availability of a draft guidance entitled "Investigational New Drug Applications for Positron Emission Tomography (PET) drugs." The draft guidance summarizes the IND process for PET drugs, makes recommendations for how to submit an IND, provides advice on expanded access options for investigational PET drugs, and describes the process for requesting permission to charge for an investigational PET drug.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the submission of INDs for PET drugs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if

such approach satisfies the requirements of the applicable statutes and regulations.

#### II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

#### III. Paperwork Reduction Act of 1995

This draft 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). INDs and requests to charge for a drug under an IND are submitted to FDA under part 312 (21 CFR part 312). NDAs and ANDAs are submitted to FDA under §§ 314.50 and 314.94 (21 CFR 314.50 and 3.14.94). The collections of information in part 312 and in §§ 314.50 and 314.94 have been approved under OMB control numbers 0910-0014, 0910-0653, 0910-0651, and 0910-0001.

#### IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: February 8, 2012.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2012-3319 Filed 2-13-12; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0805]

#### Dermatologic and Ophthalmic Drugs Advisory Committee; Amendment of Notice

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of the meeting of the Dermatologic and Ophthalmic Drugs