

—*Budget and Budget Justification 15 points.*

For FY 2011, the two criteria for the SEDS-AFI FOA will be titled and weighted as follows:

—*Approach 90 points and*  
—*Budget and Budget Justification 10 points.*

The criteria titles will match the titles found in the project description section of the FOAs. Matching titles will help applicants to better understand the connection between the two sections of the FOAs. The assigned weights better reflect what ANA considers to be the most important elements of the project application. (Legal authority: Section 803(c) of NAPA, as amended.)

ii. *ANA Evaluation Criteria:* Included here is a summary of each criterion. The FOAs will include a more detailed description of the evaluation criteria and the associated project description.

(a) *Objectives and Need for Assistance:* Under this criterion, applications will be evaluated on the applicant's community and applicant identification, connection to the community, community participation in the project development, the problem statement, and the briefly stated objectives.

(b) *Outcomes Expected:* Under this criterion, applications will be evaluated on the strength of the project outcomes expected, which include the project goal, the results and benefits expected, and one project-specific impact indicator. For language applications that are designed to teach a Native language, applicants must include an impact indicator that shows advancement of language fluency. All other language projects should provide an impact indicator that measures an increase in community interest to preserve the language.

(c) *Approach:* Under this criterion, the application will be evaluated on the strength of the project approach. This criterion includes two sub-criteria: The project strategy and the OWP. The project strategy sub-criterion includes a detailed description of the implementation plan, community involvement and outreach during implementation, and contingency planning to support project implementation. In addition, partnerships and leveraged resources will be evaluated as to their contribution within the overall strategy of project implementation and its sustainability; however, the target numbers will not be evaluated or scored. In this section reviewers will also consider organizational capacity and project sustainability. The OWP

sub-criterion includes a review of the OWP form and its strength as an effective implementation tool.

(d) *Budget:* Under this criterion, the application will be evaluated on the strength of the budget and how well it supports successful completion of the project objectives. This criterion includes a line-item budget and budget justification for each line item for each budget period.

The changes to the content of evaluation criteria, and the complementary changes to the project description section of the FOA, will more effectively guide panel reviewers and applicants on what ANA believes are critical components of a project application. (Legal authority: Section 803(c) of NAPA, as amended.)

Dated: November 22, 2010.

**Lillian Sparks,**

*Commissioner, Administration for Native Americans.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0583]

#### Agency Information Collection Activities: Proposed Collection; Comment Request; Radioactive Drug Research Committees

**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 collection of information, including 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 the information collection contained in regulations governing the use of radioactive drugs for basic informational research (21 CFR 361.1).

**DATES:** Submit either electronic or written comments on the collection of information by January 31, 2011.

**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:

Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3792, [Elizabeth.Berbakos@fda.hhs.gov](mailto:Elizabeth.Berbakos@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, including each proposed extension of an existing 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.

#### Radioactive Drug Research Committees—(OMB Control Number 0910-0053)

Under sections 201, 505, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 355, and 371), FDA has the authority to issue regulations governing the use of radioactive drugs

for basic scientific research. Section 361.1 (21 CFR 361.1) sets forth specific regulations regarding the establishment and composition of Radioactive Drug Research Committees and their role in approving and monitoring basic research studies utilizing radiopharmaceuticals. No basic research study involving any administration of a radioactive drug to research subjects is permitted without the authorization of an FDA approved Radioactive Drug Research Committee (§ 361.1(d)(7)). The type of research that may be undertaken with a radiopharmaceutical drug must be intended to obtain basic information and not to carry out a clinical trial for safety or efficacy. The types of basic research permitted are specified in the regulation, and include studies of metabolism, human physiology, pathophysiology, or biochemistry.

Section 361.1(c)(2) requires that each Radioactive Drug Research Committee shall select a chairman, who shall sign all applications, minutes, and reports of the committee. Each committee shall meet at least once each quarter in which research activity has been authorized or conducted. Minutes shall be kept and shall include the numerical results of votes on protocols involving use in human subjects. Under § 361.1(c)(3), each Radioactive Drug Research

Committee shall submit an annual report to FDA. The annual report shall include the names and qualifications of the members of, and of any consultants used by, the Radioactive Drug Research Committee, using FDA Form 2914, and a summary of each study conducted during the proceeding year, using FDA Form 2915.

Under § 361.1(d)(5), each investigator shall obtain the proper consent required under the regulations. Each female research subject of childbearing potential must state in writing that she is not pregnant, or on the basis of a pregnancy test be confirmed as not pregnant.

Under § 361.1(d)(8), the investigator shall immediately report to the Radioactive Drug Research Committee all adverse effects associated with use of the drug, and the committee shall then report to FDA all adverse reactions probably attributed to the use of the radioactive drug.

Section 361.1(f) sets forth labeling requirements for radioactive drugs. These requirements are not in the reporting burden estimate because they are information supplied by the Federal Government to the recipient for the purposes of disclosure to the public (5 CFR 1320.3(c)(2)).

Types of research studies not permitted under this regulation are also

specified, and include those intended for immediate therapeutic, diagnostic, or similar purposes or to determine the safety or effectiveness of the drug in humans for such purposes (*i.e.*, to carry out a clinical trial for safety or efficacy). These studies require filing of an investigational new drug application (IND) under 21 CFR part 312, and the associated information collections are covered in OMB Control Number 0910–0014.

The primary purpose of this collection of information is to determine whether the research studies are being conducted in accordance with required regulations and that human subject safety is assured. If these studies were not reviewed, human subjects could be subjected to inappropriate radiation or pharmacologic risks.

Respondents to this information collection are the chairperson(s) of each individual Radioactive Drug Research Committee, investigators, and participants in the studies.

The burden estimates are based on FDA's experience with these reporting and recordkeeping requirements over the past few years and the number of submissions received by FDA under the regulations.

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

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

| 21 CFR Section          | Forms          | Number of respondents | Annual frequency per response | Total annual responses | Hours per response | Total hours |
|-------------------------|----------------|-----------------------|-------------------------------|------------------------|--------------------|-------------|
| 361.1(c)(3) & (4) ..... | FDA 2914 ..... | 80                    | 1                             | 80                     | 1                  | 80          |
| 361.1(c)(3) .....       | FDA 2915 ..... | 50                    | 6.8                           | 340                    | 3.5                | 1,190       |
| 361.1(d)(8) .....       | .....          | 50                    | 6.8                           | 340                    | 0.1                | 34          |
| Total .....             | .....          | .....                 | .....                         | .....                  | .....              | 1,304       |

<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 | Annual frequency per recordkeeping | Total annual records | Hours per record | Total hours |
|-------------------|-------------------------|------------------------------------|----------------------|------------------|-------------|
| 361.1(c)(2) ..... | 80                      | 4                                  | 320                  | 10               | 3,200       |
| 361.1(d)(5) ..... | 50                      | 6.8                                | 340                  | .75              | 255         |
| Total .....       | .....                   | .....                              | .....                | .....            | 3,455       |

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

Dated: November 23, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0594]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Focus Groups as Used by the Food and Drug Administration (All Food and Drug Administration Regulated Products)

**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 collection of information, including 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 focus groups as used by FDA to gauge public opinion on all FDA-regulated products.

**DATES:** Submit either electronic or written comments on the collection of information by January 31, 2011.

**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:

Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3794, e-mail:

[Jonnalynn.capezzuto@fda.hhs.gov](mailto:Jonnalynn.capezzuto@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, including each proposed extension of an existing 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.

#### Focus Groups as Used by the Food and Drug Administration (All FDA-Regulated Products)—(OMB Control Number 0910-0497)—Extension

FDA conducts focus group interviews on a variety of topics involving FDA-regulated products, including drugs, biologics, devices, food, tobacco, and veterinary medicine.

Focus groups provide an important role in gathering information because they allow for a more indepth understanding of consumers' attitudes, beliefs, motivations, and feelings than do quantitative studies. Focus groups serve the narrowly defined need for direct and informal opinion on a specific topic and as a qualitative research tool have three major purposes:

- To obtain consumer information that is useful for developing variables and measures for quantitative studies,
- To better understand consumers' attitudes and emotions in response to topics and concepts, and
- To further explore findings obtained from quantitative studies.

FDA will use focus group findings to test and refine their ideas but will generally conduct further research before making important decisions, such as adopting new policies and allocating or redirecting significant resources to support these policies.

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

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

| Activity                     | Number of respondents | Annual frequency per response | Total annual responses | Hours per response | Total hours |
|------------------------------|-----------------------|-------------------------------|------------------------|--------------------|-------------|
| Focus Group Interviews ..... | 1,440                 | 1                             | 1,440                  | 1.75               | 2,520       |

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