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

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
201.57(f)(10) ANDAs	96	4.67	449	2	898
Total					1,762

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

In the **Federal Register** of March 9, 2004 (69 FR 11021), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

Dated: June 16, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–14078 Filed 6–21–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

International Workshop on Minor Use and Minor Species: A Global Perspective; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled ''International Workshop on Minor Use and Minor Species (MUMS): A Global Perspective.'' The workshop is the result of a partnership between FDA's Center for Veterinary Medicine (CVM) and the U.S. Department of Agriculture's (USDA's) minor use animal drug program, the National Research Support Project #7 (NRSP–7). The purpose of the workshop is to assemble international expertise to discuss the global pursuit of drug approvals for MUMS. The workshop is planned to provide several ''forums'' for discussion of the global perspectives of drug needs and drug approvals for minor species and minor uses. Areas to be discussed include data requirements for MUMS drug approvals (effectiveness, target animal safety, human food safety, environmental safety, etc.), the classification of minor species, and husbandry practices in the various regions of the world. Anticipated outcomes of the workshop include methods and strategies to improve cooperation and coordination of national and regional programs to maximize MUMS drug approvals internationally.

Date and Time: This 2-day public workshop will be held on October 7, 2004, from 8:30 a.m. to 5:45 p.m., and on October 8, 2004, from 8:30 a.m. to 12:15 p.m. Registration opens at 7:30 a.m. each day.

Location: The public workshop will be held at the DoubleTree Hotel, Plaza Room III, 1750 Rockville Pike, Rockville, MD.

The DoubleTree Hotel is accessible via the Washington, DC Metro Transit System, Red Line, and is located next to the Twinbrook Metro Station. The hotel is a short walk from the station.

Contact: Margaret Oeller, Center for Veterinary Medicine (HFV–1), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–3067, FAX: 301–827–4572, or e-mail: *moeller@cvm.fda.gov*.

Registration: Registration forms for the workshop are available from the CVM/FDA's Web site and should be completed online. If a paper copy is needed, please contact Anna Roy, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–2957, FAX: 301–827–4572, or e-mail: *aroy@cvm.fda.gov* by Wednesday, October 6, 2004. There is no registration fee for the public workshop. Because seating is limited, we recommend early registration.

If you need special accommodations due to a disability, please contact Anna Roy at least 7 days in advance of the workshop.

SUPPLEMENTARY INFORMATION: FDA's CVM, in partnership with the USDA's National Research Support Project #7 (NRSP–7), will convene a public workshop entitled ''International Workshop on Minor Use and Minor Species (MUMS): A Global Perspective.'' International representatives have been invited to speak on pertinent issues relating to product approvals for MUMS from their respective countries.

There will be an opportunity to raise additional questions and issues for discussion during open public comment periods during each day of the workshop. Prior to the meeting, the draft agenda for this public workshop will be posted on CVM's Web site at *http://www.fda.gov/cvm/default.html* and on the NRSP–7 Web site at *http://www.nrsp7.org* (FDA has verified the Web site address, but FDA is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**).

Transcripts: Transcripts of the workshop will be posted on the CVM Web site at *http://www.fda.gov/cvm/default.html*. Written copies of the transcript may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, after the public workshop, at a cost of 10 cents per page.

Questions about the workshop may be directed to Margaret Oeller, CVM, at 301–827–3067 or *moeller@cvm.fda.gov* by Tuesday, October 5, 2004.

Dated: June 15, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–14015 Filed 6–21–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1998D–0785]

Guidances for Industry on Medical Imaging Drug and Biological Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of three guidances for industry on ''Developing Medical Imaging Drug and Biological Products.'' These guidances are intended to assist developers of medical imaging drug and biological products (medical imaging agents) in planning and coordinating their clinical investigations and preparing and submitting

investigational new drug applications (INDs), new drug applications (NDAs), biologics license applications (BLAs), abbreviated new drug applications (ANDAs), and supplements to NDAs or BLAs.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidances to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request. Submit written comments on the guidances to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidances.

FOR FURTHER INFORMATION CONTACT:

Sally Loewke, Center for Drug Evaluation and Research (HFD–160), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7510, or

Kathleen Swisher, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 14, 1998 (63 FR 55067), FDA published a document announcing the availability of a draft guidance for industry entitled ''Developing Medical Imaging Drugs and Biologics.'' In a document published in the **Federal Register** of January 5, 1999 (64 FR 457), FDA reopened the comment period on the draft guidance until February 12, 1999. In a document published in the **Federal Register** of February 16, 1999 (64 FR 7561), FDA extended the comment period until April 14, 1999.

FDA received numerous written comments on the medical imaging draft guidance. In addition, the agency held public meetings on January 25 and March 26, 1999, to discuss various issues concerning the draft guidance. In the **Federal Register** of July 31, 2000 (65 FR 46674), the agency published a document announcing the availability of a revised draft guidance.

After considering the comments that FDA received on the revised draft guidance, the agency decided to revise the draft guidance, divide it into three parts to make it more user-friendly, and issue the three parts as drafts for comment. In the **Federal Register** of May 19, 2003 (68 FR 27008), FDA published a document announcing the availability of the three parts.

Part 1 of ''Medical Imaging Drug and Biological Products,'' entitled ''Conducting Safety Assessments,'' provides recommendations on conducting safety assessments of medical imaging agents. Part 2, ''Clinical Indications,'' provides recommendations on tailoring clinical development programs for medical imaging agents to reflect the use of these agents for diagnosis and monitoring of diseases and conditions. Part 3, ''Design, Analysis, and Interpretation of Clinical Studies,'' provides recommendations on designing a clinical development program for a medical imaging agent, including selecting subjects, and on acquiring, analyzing, and interpreting medical imaging data. Collectively, these guidances provide information and recommendations on how to develop all types of medical imaging agents and how to comply with certain provisions in the final rule, published in the **Federal Register** of May 17, 1999 (64 FR 26657), on the evaluation and approval of in vivo radiopharmaceuticals used in diagnosis and monitoring. Having reviewed the comments that FDA received on each of the three parts, and having made appropriate changes, the agency is issuing final versions of these guidances.

These guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidances represent the agency's current thinking on different aspects of the development of medical imaging agents. They do not create or confer any rights for or on any person and do 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**) written or electronic comments on the guidances at any time. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidances and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the documents at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

IV. The Paperwork Reduction Act of 1995

These guidances contain information collection provisions that 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 guidances would not impose any additional reporting burden because the submission of information on the safety and effectiveness of medical imaging agents in applications for marketing approval and INDs is already required by existing regulations. In fact, clarification by the guidances of FDA's standards for evaluation of medical imaging agents is expected to reduce the overall burden of information collection. FDA received no comments on the analysis of information collection burdens stated in the announcement of availability of the original draft guidance published in the **Federal Register** on October 14, 1998 (63 FR 55067). In the **Federal Register** of July 31, 2000 (65 FR 46674), the agency requested comments on the revised proposed collections of information. No comments were received.

Dated: June 16, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–14077 Filed 6–21–04; 12:56 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.