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