TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	No. of Respondents	Annual Frequency per Response [2]	Total Annual Responses [3]	Hours per Response	Total Hours
CBER (none)	134 [4]	32	4,243	2	8,486
CDER § 314.81(b)(3)(i)	386 [5]	32	12,395	2	24,790
Total					33,276

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Average number (rounded to the nearest whole number) of submissions submitted annually per sponsor. We note that some sponsors submit only once per year, whereas one sponsor had 893 submissions in 1999.
[3] Total number of Form FDA 2253 submissions to CDER and Form FDA 2253 plus Form FDA 2567 to CBER in fiscal year (FY) 1999.
[4] Number of sponsors that submitted establishment license applications and product license applications to CBER in FY 1999.
[5] Number of sponsors that submitted new drug applications (including applications for new antibiotics), abbreviated new drug applications, and abbreviated antibiotic applications in FY 1999.

In FY 1999, CDER received a total of 12,395 submissions and CBER received 4,353 submissions that would require the use of this form. FDA estimates that 2 hours would be required for an industry regulatory affairs specialist to fill out the form, collate the documentation, and send the submissions to CDER or CBER.

Electronic Submission of Promotional Materials Regarding Prescription Drugs and Biologics for Human Use

CDER and CBER are currently piloting with approximately 20 sponsors, different methods to submit postmarketing submissions of advertising and promotional labeling. FDA anticipates publishing in the **Federal Register** a draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Prescription Drug Advertising and Promotional Labeling.'' By using this suggested format for electronically submitting promotional materials, we anticipate that by January 2002, sponsors will submit about 20 percent of all materials electronically via Form FDA 2253. Further, we anticipate posting a fillable electronic Form FDA 2253 on FDA's Internet site. Applicants may then have the option to fill out the form on their computer, and with additional software, they can maintain records regarding submitted promotional materials.

Dated: December 14, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1395]

Agency Information Collection Activities; Announcement of OMB Approval; Medicated Feed Mill License

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Medicated Feed Mill License'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 6, 2000 (65 FR 59852), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0337. The approval expires on November 30, 2003. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: December 14, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1316]

Agency Information Collection Activities; Announcement of OMB Approval; Guidance for Industry on How to Use E–Mail to Submit a Request for a Meeting or Teleconference to the Office of New Animal Drug Evaluation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Guidance for Industry on How to Use E–Mail to Submit a Request for a Meeting or Teleconference to the Office of New Animal Drug Evaluation'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 21, 2000 (65 FR 57194), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0452. The approval expires on November 30, 2003. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.