

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
CDER (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 CDER in fiscal year (FY) 1999.

⁴ Number of sponsors that submitted establishment license applications and product license applications to CDER 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 CDER 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 CDER.

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

CDER and CDER 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 FDA anticipates publishing in the **Federal Register** a draft guidance for industry entitled "Providing Regulatory Submissions in Electronic Format—Prescription Drug Advertising and Promotional Labeling."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.

[FR Doc. 00-32615 Filed 12-20-00; 8:45 am]

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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>.

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-1449]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Guidance for Industry: Changes to an Approved NDA or ANDA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by January 22, 2001.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry: Changes to an Approved NDA or ANDA

On November 21, 1997, the President signed the Food and Drug Administration Modernization Act (the Modernization Act) (Pubic Law 105-115) into law. Section 116 of the Modernization Act amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 506A (21 U.S.C. 356a), which describes requirements and procedures for making and reporting manufacturing changes to approved new drug applications (NDA's) and abbreviated new drug

applications (ANDA's), to new and abbreviated animal drug applications, and to license applications for biological products.

The guidance is intended to assist applicants in determining how they should report changes to an approved NDA or ANDA under section 116 of the Modernization Act, which provides requirements for making and reporting manufacturing changes to an approved application and for distributing a drug product made with such changes.

The guidance provides recommendations to holders of approved NDA's and ANDA's who intend to make postapproval changes in accordance with section 506A of the act. The guidance covers recommended reporting categories for postapproval changes for drugs, other than specified biotechnology and specified synthetic biological products. Recommendations are provided for postapproval changes in: (1) Components and composition, (2) sites, (3) manufacturing process, (4) specification(s), (5) package, (6) labeling, and (7) miscellaneous changes.

Some of the basic elements of section 506A of the act are as follows:

A drug made with a manufacturing change, whether a major manufacturing change or otherwise, may be distributed only after the applicant validates the effects of the change on the identity, strength, quality, purity, and potency of the drug as these factors may relate to the safety or effectiveness of the drug (sections 506A(a)(1) and (b) of the act). This section recognizes that additional testing, beyond testing to ensure that an approved specification is met, is required to ensure unchanged identity, strength, quality, purity, or potency as these factors may relate to the safety or effectiveness of the drug.

A drug made with a major manufacturing change may be distributed only after the applicant submits a supplemental application to FDA and the supplemental application is approved by the agency. The application is required to contain information determined to be appropriate by FDA and include the information developed by the applicant when "validating the effects of the change" (section 506A(c)(1) of the act).

A major manufacturing change is a manufacturing change determined by FDA to have substantial potential to adversely affect the identity, strength, quality, purity, or potency of the drug as these factors may relate to the safety or effectiveness of the drug. Such changes include: (1) A change made in the qualitative or quantitative formulation of the drug involved or in the specifications in the approved

application or license unless exempted by FDA by regulation or guidance; (2) a change determined by FDA by regulation or guidance to require completion of an appropriate clinical study demonstrating equivalence of the drug to the drug manufactured without the change; and (3) other changes determined by FDA by regulation or guidance to have a substantial potential to adversely affect the safety or effectiveness of the drug (section 506A(c)(2) of the act).

FDA may require submission of a supplemental application for drugs made with manufacturing changes that are not major (section 506A(d)(1)(B) of the act) and establish categories of manufacturing changes for which a supplemental application is required (section 506A(d)(1)(C) of the act). In such a case the applicant may begin distribution of the drug 30 days after FDA receives a supplemental application unless the agency notifies the applicant within the 30-day period that prior approval of the application is required (section 506A(d)(3)(B)(i) of the act). FDA may also designate a category of manufacturing changes that permit the applicant to begin distributing a drug made with such changes upon receipt by the agency of a supplemental application for the change (section 506A(d)(3)(B)(ii) of the act). If FDA disapproves a supplemental application, the agency may order the manufacturer to cease the distribution of drugs that have been made with the disapproved change (section 506A(d)(3)(B)(iii) of the act).

FDA may authorize applicants to distribute drugs without submitting a supplemental application (section 506A(d)(1)(A) of the act) and may establish categories of manufacturing changes that may be made without submitting a supplemental application (section 506A(d)(1)(C) of the act). The applicant is required to submit a report to FDA on such a change and the report is required to contain information the agency deems to be appropriate and information developed by the applicant when validating the effects of the change. FDA may also specify the date on which the report is to be submitted (section 506A(d)(2)(A) of the act). If during a single year an applicant makes more than one manufacturing change subject to an annual reporting requirement, FDA may authorize the applicant to submit a single report containing the required information for all the changes made during the year (annual report) (section 506A(d)(2)(B) of the act).

Section 506A of the act provides FDA with considerable flexibility to