Dated: March 5, 1997

William K. Hubbard,

Associate Commissioner for Policy Coordination

[FR Doc. 97–6356 Filed 3–12–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96N–0192]

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

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 April 14, 1997.

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

FOR FURTHER INFORMATION CONTACT: Linda L. Brna, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–3158.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance:

Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use; Use of Form FDA 356h

FDA is the Federal agency charged with the responsibility for determining that drugs, including antibiotic drugs, and biologics are safe and effective. Manufacturers of a drug, biologic, or an antibiotic drug for human use must file applications for FDA approval of the product prior to introducing it into interstate commerce. Statutory authority for the collection of this information is provided by sections 505(a), (b), and (j) and 507 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(a), (b), and (j) and 357) and section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262). All manufacturers of new drugs and antibiotics for human use regulated under the act must submit an application for review and approval to the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER) prior to marketing a drug or antibiotic in interstate commerce (21 CFR 314.50). All manufacturers of generic drugs, including generic antibiotic drugs for human use, regulated under the act must submit an abbreviated new drug application (ANDA) to CDER or CBER or an abbreviated antibiotic drug application (AADA) to CDER for review and approval prior to marketing a generic drug in interstate commerce (21 CFR 314.94). Most manufacturers of biological products regulated under the PHS Act must submit an establishment license application and a product license application or a biologics license application for review and approval to CBER prior to marketing a biological product in interstate commerce (21 CFR 601.2). Blood and blood components fall within the category of biological products. All establishments collecting and/or preparing blood and blood components for sale or distribution in interstate commerce are subject to the licensing application provisions of section 351 of the PHS Act. Manufacturers of a drug, biologic, or an antibiotic drug for human use are required to file supplemental applications for all important changes to applications previously approved prior to implementing such changes (21 CFR 314.70, 314.71, 314.97, and 601.12).

Form FDA 356h has been revised for CDER-regulated products to include identification of different types of supplemental applications. It has also been modified to include a section for establishment information pertaining to CBER-regulated products and the CBER licensing process.

The information provided by manufacturers with the revised application form is necessary for FDA to carry out its mission of protecting the public health and helping to ensure that drugs, biologics, and antibiotics for human use have been shown to be safe and effective. Form FDA 356h was developed initially as a checklist to assist manufacturers in filing a drug application and has been previously used only by manufacturers of products regulated under the act. The revised form has been harmonized for use by manufacturers of products regulated under the act or under the PHS Act and will be used by industry regulated by both CDER and CBER. The harmonized application form serves primarily as a checklist for firms to gather and submit to the agency studies and data that have been completed. The checklist helps to ensure that the application is complete and contains all the necessary information, so that delays due to lack of information may be eliminated. The form will also provide key information to the agency for efficient handling and distribution to the appropriate staff for review. The revised form will replace a number of different application forms that are now used for these products and is intended to help harmonize the application process.

In the Federal Register of October 1, 1996 (61 FR 51285), the agency requested comments on the proposed collection of information using the harmonized application form. FDA received five responses to the docket, all of which were generally supportive of the harmonized application form. One comment expressed concern that the requirement to select a single supplement type on the form would result in an increased reporting burden. The comment indicated that selection of a single supplement type would require the filing of multiple supplements in order to respond to an agency information request letter containing several diverse issues. The comment may have misunderstood the distinction between a supplement to an approved application and an amendment to a pending application. A response to an agency information request letter is an amendment to a pending application, no matter how many individual subjects are addressed. This is clarified in the instruction sheet for the form.

There were also a number of editorial comments on the form itself. Some of these have resulted in minor modifications to the form. Other editorial comments and requests for clarification are addressed in the instructions for use of the form.

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

Estimated Annual Reporting Burden					
Type of Response[1]	No. of Respondents[2]	Annual Frequency per Response[3]	Total Annual Responses[4]	Hours per Response	Total Hours
NDA[5]	162	22.9	3,715	40	148,600
ANDA[6] and AADA[7]	350	18.6	6,517	40	260,680
ELA[8] and PLA[9]	391	4.9	1,905	40	76,200
Total Burden Hours					485,480

There are no capital costs or operating and maintenance costs associated with this collection.
[1] Includes original applications and their amendments and supplemental applications
[2] Number of sponsors submitting applications during fiscal year (FY) 95
[3] Average number of applications submitted per sponsor
[4] Total applications submitted during FY 95
[5] New Drug Application (includes applications for new antibiotic drugs)
[6] Abbreviated New Drug Application
[7] Abbreviated Antibiotic Drug Application
[8] Establishment License Application
[9] Product License Application

In FY 95, CDER received a total of 10,232 submissions and CBER received 1,905 submissions that would require use of this application form. FDA estimates that 40 hours would be needed for an industry regulatory affairs specialist to fill out the harmonized form, collate the documentation, and submit the application to CDER or CBER.

Dated: March 6, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–6360 Filed 3–12–97; 8:45 am]

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[Docket No. 84N–0102]

Cumulative List of Orphan Drug and Biological Designations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a cumulative list of designated orphan drugs and biologics as of December 31, 1996. FDA has announced the availability of previous lists, which are brought up-to-date monthly, identifying the drugs and biologicals granted orphan-drug designation under the Federal Food, Drug, and Cosmetic Act (the act).

ADDRESSES: Copies of the list of current orphan-drug designations and of any future lists are or will be available from the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, and the Office of Orphan Products Development (HF–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3666.

FOR FURTHER INFORMATION CONTACT: Peter L. Vaccari, Office of Orphan Products Development (HF–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0983.

SUPPLEMENTARY INFORMATION: FDA's Office of Orphan Products Development (OPD) reviews and takes final action on applications submitted by sponsors seeking orphan-drug designation under section 526 of the act (21 U.S.C. 360bb). In accordance with this section of the act, which requires public notification of designations, FDA maintains a list of designated orphan drugs and biologicals. This list is made current on a monthly basis and is available upon request from OPD (contact identified above). At the end of each calendar year, the agency publishes an up-to-date cumulative list of designated orphan drugs and biologicals, including the names of designated compounds, the specific disease or condition for which the compounds are designated, and the sponsors' names and addresses.

The list that is the subject of this notice consists of designated orphan drugs and biologicals through December 31, 1996, and, therefore, brings the April 22, 1996 (61 FR 17708) publication up to date. This list is available on request from FDA's Dockets Management Branch (address above). Those requesting a copy should specify the docket number found in brackets in the heading of this document.

The orphan-drug designation of a drug or biological applies only to the sponsor who requested the designation. Each sponsor interested in developing an orphan drug or biological must apply for orphan-drug designation in order to obtain exclusive marketing rights. Any request for designation must be received by FDA before the submission of a marketing application for the proposed indication for which designation is requested. (See 53 FR 47577, November 23, 1988.) Copies of the regulations (see 57 FR 62076, December 29, 1992) for use in preparing an application for orphan-drug designation may be obtained from OPD (address above).

The names used in the cumulative list for the drug and biological products that have not been approved or licensed for marketing may not be the established or proper names approved by FDA for these products if they are eventually approved or licensed for marketing. Because these products are investigational, some may not have been reviewed for purposes of assigning the most appropriate established proper name.

Dated: March 5, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–6357 Filed 3–12–97; 8:45 am]

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[Docket No. 96N–0283]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information regarding Regulations under the Federal Import Milk Act, has been approved by the Office of Management and Budget (OMB), under the Paperwork Reduction