

DMB

| | |
|------------------|--------------------|
| Signature | 10/20/99 |
| Publication Date | 10/21/99 |
| Certifier | <i>[Signature]</i> |

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-4202]

Agency Information Collection Activities; Proposed Collection; Comment Request; Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use— Form FDA 356h

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the application form, Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use, Form FDA 356h, and a related regulation. This form applies to a wide range of products for human use that are regulated by both the Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER) including drugs and biologics.

DATES: Submit written comments on the collection of information by (*insert date 60 days after date of publication in the Federal Register*).

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency request or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use; Form FDA 356h (OMB Control Number 0910-0338)—Extension

FDA is the Federal agency charged with responsibility for determining that drugs, including antibiotic drugs, and biologics are safe and effective. Manufacturers of a drug, or biologic 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 section 505(a), (b), and (j) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(a), (b), and (j)) and section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262).

Manufacturers of new drugs for human use regulated under the act must submit a new drug application (NDA) for review and approval to CBER or CDER prior to marketing a drug in interstate commerce (§ 314.50 (21 CFR 314.50)). Manufacturers of generic drugs regulated under the act must submit a abbreviated new drug application (ANDA) for review and approval to CDER prior to marketing a generic drug in interstate commerce (§ 314.94 (21 CFR 314.94)).

Manufacturers of biological products regulated under the PHS Act must submit an establishment license application (ELA) and a product license application (PLA) or biologics license application (BLA) for review and approval to CBER prior to marketing a biological product in interstate commerce (§ 601.2 (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. Applicants are required to report to FDA any transfer of ownership of an NDA (21 CFR 314.72). Applicants are required to report a change in ownership of an ANDA (21 CFR 314.99(a)). Manufacturers of a drug or biologic for human use are required to file supplemental applications for certain changes to applications previously approved (21 CFR 314.70, 314.71, 314.97, and 601.12). The form is also submitted with an amendment to an unapproved original application or supplemental application, and a presubmission or resubmission of information pertaining to an application.

The information provided by manufacturers with the application form is necessary for FDA to carry out its mission of protecting the public health and helping to ensure that drugs and biologics for human use have been shown to be safe and effective. Form FDA 356h was developed initially as a checklist to assist manufacturers in filling a drug application and has been previously used only by manufacturers of products regulated under the act. In the **Federal Register** of July 8,

1997 (62 FR 36558), FDA announced the availability of the revised Form FDA 356h. The form was revised as a “Reinventing Government” initiative to harmonize application procedures between CBER and CDER. The 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 provides key information to the agency for efficient handling and distribution to the appropriate staff for review. For biologics manufacturers, the form will replace a number of different ELA and PLA forms that were formerly used for these products. The information collection burden for various ELA and PLA forms is covered under OMB Control No. 0910–0124.

There are an estimated 343 licensed biologics manufacturers. However, not all manufacturers will have any submissions in a given year and some may have multiple submissions. The annual responses are based on submissions received by FDA in 1998. The time estimated to prepare an ELA/PLA or BLA under § 601.2 for CBER approval to market a new product is based on information provided by industry. The time required for preparing an ELA/PLA or BLA includes the estimate for filling out the form. The estimated average burden hours for the other submissions using Form 356h to CBER is based on past FDA experience and includes the time to fill out the form and collate the documentation. The average burden hours also include the time to prepare an amendment submitted to CBER. The estimated burden hours to prepare a supplement to CBER (§ 601.12) are reported under OMB Control No. 0910–0315.

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

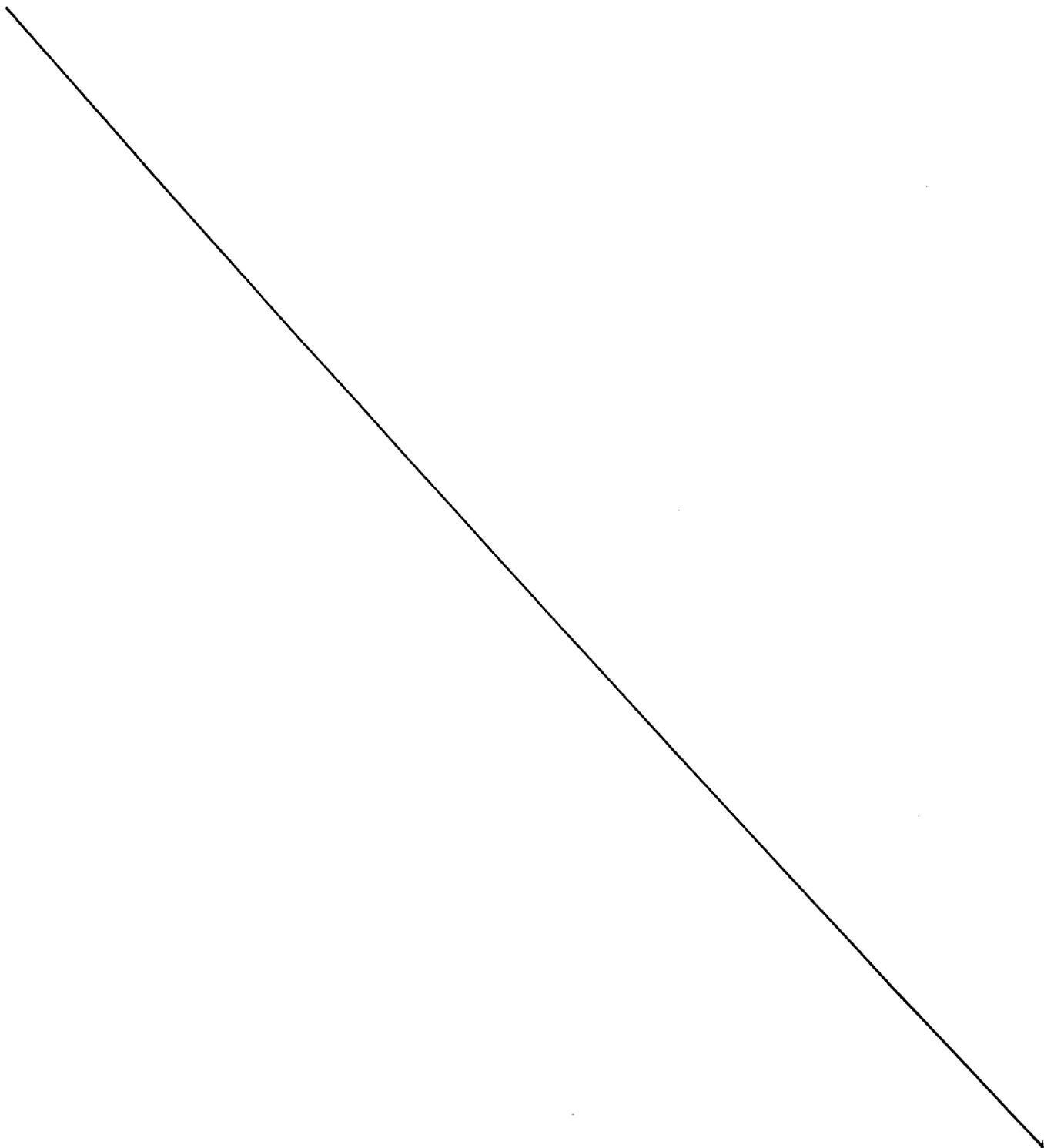
TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN FOR BIOLOGICS¹

| 21 CFR/FDA Form | No. of Respondents | Total Annual Responses | Hours per Response | Total Hours |
|-----------------|--------------------|------------------------|--------------------|-------------|
| 601.2 | 343 | 84 | 1,600 | 134,400 |
| Form 356h | 343 | 4,947 | 16 | 79,152 |
| Total | | | | 213,552 |

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

There are 483 drug applicants that submitted the form. The annual responses are based on submissions received by FDA in 1997 and 1998. The estimated average burden hours for the

submissions using Form 356h to CDER is based on past FDA experience and includes the time to fill out the form and collate the documentation. The estimated burden hours to prepare an NDA (§ 314.50); an ANDA (§ 314.94); supplements (21 CFR 314.70, 314.71, and 314.97); and amendments (21 CFR 314.60 and 314.96) are approved under OMB Control No. 0910-0001.



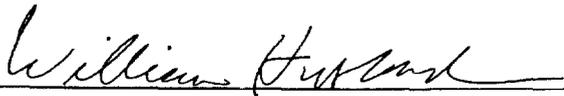
FDA estimates the burden of this collection of information as follows:

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN FOR HUMAN DRUGS¹

| 21 CFR Part/FDA Form | No. of Respondents | Total Annual Responses | Hours per Response | Total Hours |
|----------------------|--------------------|------------------------|--------------------|--------------------|
| Form 356h Total | 483 | 16,221 | 24 | 389,304 389,304 |

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: October 13, 1999



William K. Hubbard
Senior Associate Commissioner for Policy, Planning and Legislation

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

BILLING CODE 4160-01-F

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

