Committee name	Code
Vaccines and Related Biological Products Advisory Committee	12391
Transmissible Spongiform Encephalopathies Advisory Committee	12392

Dated: December 11, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–33097 Filed 12–18–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0503]

Agency Information Collection Activities: Proposed Collection

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 reinstatement of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on requirements for submission of a new animal drug application (NADA).

DATES: Submit written comments on the collection of information by February 17, 1998.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1686.

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 requests 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 reinstatement 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.

New Animal Drug Application (NADA), Form FDA 356 V, 21 CFR Part 514, (OMB Control number 0910–0032—Reinstatement)

Description: FDA has the responsibility under the Federal Food, Drug, and Cosmetic Act (the act), for the approval of new animal drugs that are safe and effective. Section 512(b) of the act (21 U.S.C. 360b(b)) requires that a sponsor submit and receive approval of a NADA, before interstate marketing is allowed. The regulations implementing statutory requirements for NADA approval have been codified under 21 CFR part 514. NADA applicants generally use a single form, FDA 356 V. The NADA must contain, among other things, safety and effectiveness data for the drug, labeling, a list of components, manufacturing and controls information, and complete information on any methods used to determine residues of drug chemicals in edible tissues. While the NADA is pending, an amended application may be submitted for proposed changes. After an NADA has been approved, a supplemental application must be submitted for certain proposed changes, including changes beyond the variations provided for in the NADA and other labeling changes. An amended application and a supplemental application may omit statements concerning which no change is proposed. This information is reviewed by FDA scientific personnel to ensure that the intended use of an animal drug, whether as a pharmaceutical dosage form, in drinking water, or in medicated feed, is safe and effective. The respondents are pharmaceutical firms that produce veterinary products and commercial feed mills.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Form No.	21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Form FDA 356 V	514.1 and 514.6	190	6.76	1,824	211.6	271,694
	514.8 and 514.9				30	8,520
	514.11				1	1,824
Total burden hours						282,038

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

The estimate of the burden hours required for reporting are based on fiscal year 1996 data. The burden estimate includes original NADA's, supplemental NADA's and amendents to unapproved applications.

Dated: December 10, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–33098 Filed 12–18–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0485]

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 (the PRA).

DATES: Submit written comments on the collection of information by January 20, 1998.

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: Desk Officer for FDA.

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

Shipment of a Blood Product Prior to Completion of Testing for Hepatitis B Surface Antigen (HbsAg) (21 CFR 610.40(b)); and Shipment of Blood Products Known Reactive for HbsAg (21 CFR 610.40(d))—(OMB Control Number 0910–0168—Reinstatement)

Under sections 351 and 361 of the Public Health Service Act (42 U.S.C. 262 and 42 U.S.C. 264), FDA prescribes standards designed to ensure the safety, purity, potency, and effectiveness of biological products including blood and blood components and to prevent the transmission of communicable diseases. To accomplish this, FDA requires, among other things, that each unit of Whole Blood or Source Plasma be tested by a licensed serologic test for hepatitis B surface antigen (HbsAg). Section 610.40(b)(4) (21 CFR 610.40(b)(4)) permits preapproved or emergency shipments of blood products for further manufacturing before the test for HbsAg is completed. To obtain approval for such shipments, the collection facility must submit a description of the control procedures to be used by the collection facility and manufacturer. Proper control procedures are essential to ensure the safe shipment, handling, quarantine of untested or incompletely tested blood products, communication of test results, and appropriate use or disposal of the blood products based on the test results. Section 610.40(d)(1) and (d)(2) requires that a collection facility notify FDA of each shipment of HbsAg reactive source blood, plasma, or serum for manufacturing into hepatitis B vaccine and licensed or unlicensed in vitro diagnostic biological products, including clinical chemistry control reagents. The reporting requirements inform FDA of the shipment of potentially infectious biological products that may be capable of transmitting disease. The respondent's for this information collection are the blood collection facilities that are shipping hepatitis B reactive products. FDA's monitoring of such activity is essential should any deviations occur that may require immediate corrective action to protect public safety. The labeling helps ensure that product is safely and appropriately handled and used by the collection facility, shipper, and manufacturer.

Only a few firms are actually engaged in shipping hepatitis B reactive products and making the reports required by § 610.40. Also, there are very few to no emergency shipments per year related to further manufacturing and the only product currently shipped prior to completion of hepatitis B testing is a licensed product, Source Leukocytes. Shipments of Source Leukocytes are preapproved under the product license applications and do not require notification for each shipment. Currently, there have been no respondents reporting emergency or preapproved shipments (§ 610.40(b)). However, FDA is listing one report per year for emergency or preapproved shipments to account for the possibility of future emergency shipments.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
610.40(b)[2]	1	1	1	0.5	0.5
610.40(d)[3]	6	8.5	51	0.5	25.5
TOTAL					26

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

[2] This notice involves a brief letter and an enclosure. The letter identifies who is making the shipment, to whom shipped, the nature of the emergency, the kind and quantity shipped, and date of shipment. The enclosure is a copy of the shippers written standard operating procedures for handling, labeling storage, and shipment of contaminated (contagious) product. The burden for development and maintenance of standard operating procedures is approved under OMB No. 0910–0116. Preparation of the notice and duplication of standard operating procedure documents is estimated at one half hour per notice.

[3] The notice of reactive product shipment is limited to information on: the identity of the kind and amount of source material shipped; the name and address of the consignee; the date of shipment; and the manner in which the source material is labeled.

FDA has calculated no additional burden in this information collection package for the labeling requirements in § 610.40(d) because the information and statements on the label necessary for public disclosure and safety are provided by FDA in these regulations. Under 5 CFR 1320.3(c)(2), the public disclosure of information originally