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: May 2, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 01–11452 Filed 5–7–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0006]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; New Animal Drug Application, Form FDA 356 V

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 June 7, 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: 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 compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

New Animal Drug Application, Form FDA 356 V— 21 CFR Part 514 (OMB Control No. 0910–0032)—Extension

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 new animal drug application (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]

21 CFR section	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
514.1 and 514.6	190	8.33	1,582	211.6	334,751
514.8	190	8.33	1,582	30	47,460
514.11	190	8.33	1,582	1	1,582
Total					383,793

[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 1999 data. The burden estimate includes original NADAs, supplemental NADAs, and amendments to unapproved applications.

Dated: May 2, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 01–11454 Filed 5–7–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0194]

Draft Guidance for Industry on the Statistical Aspects of the Design, Analysis, and Interpretation of Chronic Rodent Carcinogenicity Studies of Pharmaceuticals; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Statistical Aspects of the Design, Analysis, and Interpretation of Chronic Rodent Carcinogenicity Studies of Pharmaceuticals.'' The purpose of this document is to provide guidance to sponsors on the design of animal carcinogenicity experiments, methods of statistical analysis of tumor data, interpretation of study results, presentation of data and results in reports, and the submission of tumor data to FDA statistical reviewers in the Center for Drug Evaluation and Research (CDER).

DATES: Submit written comments on the draft guidance by August 6, 2001. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Karl K. Lin, Center for Drug Evaluation and Research (HFD–715), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3093.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Statistical Aspects of the Design, Analysis, and Interpretation of Chronic Rodent Carcinogenicity Studies of Pharmaceuticals.'' Assessment of the risk of drug exposure in humans includes an assessment of carcinogenicity in tests in rodents. In a carcinogenicity study of a new drug using a series of increasing dose levels, statistical tests are an important component of the analysis. The Division of Biometrics in the Office of Biostatistics, CDER is responsible for conducting statistical reviews of long-term animal (rodent) carcinogenicity studies of pharmaceuticals submitted by drug sponsors to FDA.

In statistical reviews of carcinogenicity studies, statisticians evaluate the validity of the designs and the appropriateness of methods of data analysis used by the sponsor. They also use raw study data in electronic form to perform additional statistical analyses.

The purpose of this document is to provide guidance to sponsors on statistical issues related to the design of animal carcinogenicity experiments, methods of analysis of tumor data, interpretation of study results, presentation of data and results in reports, and the submission of tumor data to FDA statistical reviewers.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). The draft guidance represents the agency's current thinking on the statistical aspects of the design, analysis, and interpretation of chronic rodent carcinogenicity studies of pharmaceuticals. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: April 30, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01–11450 Filed 5–7–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

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

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a list of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

Substance Abuse Prevention and Treatment (SAPT) Block Grant Application Guidance and Instructions, FY 2002–2004 (OMB No. 0930–0080, Revision)

Sections 1921 through 1935 of the Public Health Service Act (U.S.C. 300x–21 to 300x–35) provide for annual allotments to assist States to plan, carry out, and evaluate activities to prevent and treat substance abuse and for related activities. Under the provisions of the law, States may receive allotments only after an application is submitted and approved by the Secretary, DHHS. For the federal fiscal year 2002–2004 SAPT block grant application cycles, the Substance Abuse and Mental Health Services Administration (SAMHSA) will provide States with revised application guidance and instructions to implement changes made by Public Law 106–310, signed by the President on October 17. Revisions to the previously-approved application resulting from the new SAMHSA authorizing legislation reflect the following changes: (1) Section 1922(a) under which States were required to use 35% of the funds on drug related activities and 35% on alcohol related activities (42 U.S.C. 300x–22) is repealed. (2) The Section 1925 requirement for the States to maintain a revolving fund of $100,000 to assist with half way houses for persons recovering from drug or alcohol abuse is now made optional (42 U.S.C. 300x–25). (3) Section 1930, which requires the States to maintain their financial support for substance abuse services at a level equal to the average of what they had spent the previous two years, is amended to permit non-recurring expenditures for a singular purpose to be excluded from the calculation of the Maintenance of Effort (MOE) requirement (42 U.S.C. 300x–30). (4) Section 1952 is amended to allow any amount paid to a State for a fiscal year to be available for obligation and expenditure until the end of the fiscal year following the fiscal year for which the amounts were paid, in effect giving a State two years to obligate and spend (42 U.S.C. 300x–62).

In addition, changes are being made to the annual reporting requirements associated with Section 1926 (42 U.S.C. 300x–26), which requires States to have in effect a law prohibiting access and distribution of tobacco products to minors under age 18. In Section II, the following changes are being made with respect to Goal #8 and Attachment G: (1) In Goal #8, States will not be required to report on activities that were reported in previous applications (i.e., the requirement to report on prior year compliance information is eliminated). (2) In Attachment G: (a) questions are re-ordered so they are in chronological order to facilitate reporting on compliance activities; (b) seven of the nine questions are revised to define more precisely the information that SAMHSA needs in order to review and approve applications and eliminate duplication in State reporting; (c) Matrix