additive products. It did so by authorizing PTO to extend the patent term by a portion of the time during which FDA's safety and effectiveness review prevented marketing of the product. The length of the patent term extension is generally limited to a maximum of 5 years, and is calculated by PTO based on a statutory formula. When a patent holder submits an application for patent term extension to PTO, that agency requests information from FDA, including the length of the regulatory review period for the patented product. If PTO concludes that the product is eligible for patent term extension, FDA publishes a document in the **Federal Register**, which describes the length of the regulatory review period, and the dates used to calculate that period. Interested parties may request, under § 60.24 (21 CFR 60.24), revision of the length of the regulatory review period, or may petition under § 60.30 (21 CFR 60.30) to reduce the regulatory review period by any time where marketing approval was not pursued with ''due diligence. '' The statute defines due diligence as ''that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period. '' As provided in § 60.30(c), a due diligence petition ''shall set forth sufficient facts, including dates if possible, to merit an investigation by FDA of whether the applicant acted with due diligence. '' Upon receipt of a due diligence petition, FDA reviews the petition and evaluates whether any change in the regulatory review period is necessary. If so, the corrected regulatory review period is published in the **Federal Register**. A due diligence petitioner not satisfied with FDA's decision regarding the petition may, under § 60.40 (21 CFR 60.40), request an informal hearing for reconsideration of the due diligence determination. Petitioners are likely to include persons or organizations having knowledge that FDA's marketing permission for that product was not actively pursued throughout the regulatory review period. The information collection for which an extension of approval is being sought is the use of the statutorily created due diligence petition.

Since 1992, seven requests for revision of the regulatory review period have been submitted under § 60.24. Three regulatory review periods have been altered. Two due diligence petitions have been submitted to FDA under § 60.30. There have been no requests for hearings under § 60.40 regarding the decisions on such petitions.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Part	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
60.24(a)	7	1	7	100	700
60.30	2	0	2	50	100
60.40	0	0	0	0	0
Total					800

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

Dated: May 12, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 04–11252 Filed 5–18–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0179]

Agency Information Collection Activities; Proposed Collection; Comment Request; New Animal Drug Application, FDA Form 356 V

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 reporting requirements for sponsors submitting a new animal drug application (NADA), for marketing a drug for animal use.

DATES: Submit written or electronic comments on the collection of information by July 19, 2004.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (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: Denver Presley, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

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 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 set forth in this document.

With respect to the proposed collection of information, FDA invites comments on these topics: (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, FDA Form 356 V—21 CFR Part 514 (OMB Control Number 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 an NADA, before interstate marketing is allowed. The regulations implementing statutory requirements for NADA approval have been codified under part 514 (21 CFR part 514). NADA applicants generally use a single form, FDA 356V. 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	7.39	1405	211.6	297,298
514.8	190	7.39	1405	30	42,150
514.11	190	7.39	1405	1	1,405
Total burden hours					340,853

[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 2003 data. The burden estimate includes original NADAs, supplemental NADAs and amendments to unapproved applications.

Dated: May 12, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 04–11253 Filed 5–18–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0228]

Guidance for Industry on Fixed Dose Combination and Co-Packaged Drug Products for Treatment of HIV; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Fixed Dose Combination and Co-Packaged Drug Products for Treatment of HIV.'' This guidance is intended to encourage sponsors to develop fixed dose combinations (FDC) and co-packaged products for the treatment of human immunodeficiency virus (HIV) infection. The availability of combination products may help to improve patient adherence to and facilitate distribution programs for treatment regimens for HIV.

DATES: Submit written or electronic comments on the draft guidance by July 19, 2004. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (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 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Debra B. Birnkrant, Center for Drug Evaluation and Research (HFD–530), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301 827–2330.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Fixed Dose Combination and Co-Packaged Drug Products for Treatment of HIV.'' This guidance is intended to encourage the development of fixed dose combination (FDC) and co-packaged products for the treatment of human immunodeficiency virus (HIV). The guidance addresses the agency's current thinking regarding the types of information that should be provided in an application seeking approval for an