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

FDC or co-packaged product for the treatment of HIV.

Combination therapy is essential for the treatment of HIV/AIDS. At least three active drugs, usually from two different classes, are required to suppress the virus, allow recovery of the immune system, and reduce the emergence of HIV resistance. In the United States and developing countries, simplified HIV regimens in the form of co-packaged drugs (such as blister packs) or FDCs may facilitate distribution of antiretroviral therapies and improve patient adherence to the regimens.

Although there are more than 20 unique antiretroviral drugs approved in the United States, only a few are approved for use as FDC products, and none are approved as co-packaged products. Some antiretrovirals should not be combined due to overlapping toxicities and potential viral antagonism. Other antiretrovirals should not be used in pregnant women and other special populations. It is important, therefore, that possible combinations of these products be evaluated for safety and efficacy in the various populations that may have need of them.

Recently, newer FDCs that have not been approved by FDA have received attention, and some are being promoted for use in resource poor nations where HIV/AIDS has reached epidemic proportions. These FDCs may offer cost advantages and allow simplified dosing because all three drugs are in one pill. However, the safety, efficacy, and quality of these products have not been evaluated by FDA. Products whose safety, efficacy, and quality do not conform to expected standards may pose a threat to individual patients by increasing the chances of substandard performance, which may lead not only to treatment failure, but also to the development and spread of resistant virus.

FDA is prepared to move swiftly to evaluate such products when applications for them are submitted for approval. This guidance seeks to clarify what regulatory requirements would be applied to such applications, what issues might be of concern, and how these should be addressed. Different considerations apply depending on whether a sponsor owns or has a right of reference to all of the data required to support an application or a sponsor plans to rely on literature or the FDA's findings of safety and effectiveness for an approved drug. Where appropriate, this guidance addresses the issues associated with these different scenarios.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on FDC and co-packaged products for treating HIV infection. 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 written comments on the guidance to the Division of Dockets Management (see **ADDRESSES**). Two copies of mailed 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 guidance and received comments are available for public examination in the Division of Dockets Management 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: May 14, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–11364 Filed 5–17–04; 11:05 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0050]

Over-the-Counter Drug Products; Safety and Efficacy Review; Additional Dandruff Control Ingredient; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of eligibility; request for data and information; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to August 16, 2004, the comment period for the safety and effectiveness review of piroctone olamine, 0.05 percent to 0.5 percent and 0.1 percent to 1.0 percent, for use as a dandruff control single active ingredient in leave-on and rinse-off dosage forms, respectively. FDA published a notice of eligibility and call-for-data for safety and effectiveness data and information on piroctone olamine in the **Federal Register** of February 18, 2004. FDA is taking this action in response to a request for extension of the comment period to allow interested persons additional time to submit data and information on the safety and effectiveness of piroctone olamine as a dandruff control single active ingredient.

DATES: Submit data, information, and general comments by August 16, 2004.

ADDRESSES: Submit written comments, data, and information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments, data, and information to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Michael L. Koenig, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2222.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 18, 2004 (69 FR 7652), FDA published a notice of eligibility and call-for-data for safety and effectiveness information on piroctone olamine, 0.05 percent to 0.5 percent and 0.1 percent to 1.0 percent, for use as a dandruff control single active ingredient in leave-on and rinse-off dosage forms, respectively. FDA requested that all data, information, and general comments be submitted by May 18, 2004.

II. Extension of Time

On April 16, 2004, Keller and Heckman LLP, on behalf of Clariant GmbH, requested a 90-day extension beyond the May 18, 2004, deadline for the submission of safety and effectiveness data concerning piroctone olamine (Ref. 1). The request stated that additional time is needed to assemble a comprehensive submission for this ingredient. FDA considers an extension of time for submission of data, information, and general comments concerning the safety and effectiveness of piroctone olamine to be in the public interest. Accordingly, FDA is extending the comment period for 90 days to August 16, 2004, as requested.

III. Comments

Interested persons should submit comments, data, and general information to the Division of Dockets Management (see **ADDRESSES**) by August 16, 2004. Submit three copies of all