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

comments, data, and information. Individuals submitting written information, or any individuals or entities submitting electronic comments, may submit one copy. Submissions are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by supporting information. Received submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Information submitted after the closing date will not be considered except by petition under 21 CFR 10.30.

IV. Marketing Policy

Under § 330.14(h), any product containing the conditions for which data and information are requested may not be marketed as an OTC drug in the United States at this time unless it is the subject of an approved new drug application or abbreviated new drug application.

V. Reference

The following reference is on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Comment No. EXT1.

Dated: May 12, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 04–11248 Filed 5–18–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002D–0326]

International Cooperation on Harmonization of Technical Requirements for Approval of Veterinary Medicinal Products; Final Guidance for Industry on Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Testing; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry (#149) entitled ''Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Testing'' (VICH GL33). This guidance has been developed by the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This guidance outlines a recommended testing approach to assure human food safety following the consumption of food products derived from animals treated with veterinary drugs.

DATES: Submit written or electronic comments at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Comments should be identified with the full title of the guidance and the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Louis T. Mulligan, Center for Veterinary Medicine (HFV–153), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6984, e-mail: *lmulliga@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical procedures for the development of pharmaceutical products. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonization of Technical Requirements for Approval of Pharmaceuticals for Human Use for several years to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the European Commission, European Medicines Evaluation Agency; European Federation of Animal Health; Committee on Veterinary Medicinal Products; the FDA; the U.S. Department of Agriculture; the Animal Health Institute; the Japanese Veterinary Pharmaceutical Association; the Japanese Association of Veterinary Biologics; and the Japanese Ministry of Agriculture, Forestry and Fisheries.

Four observers are eligible to participate in the VICH Steering Committee: One representative from the Government of Australia/New Zealand, one representative from the industry in Australia/New Zealand, one representative from the Government of Canada, and one representative from the industry of Canada. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation for Animal Health (IFAH). An IFAH representative also participates in the VICH Steering Committee meetings.

II. Guidance on General Testing

In the **Federal Register** of September 4, 2002 (67 FR 56570), FDA published the notice of availability of the VICH draft guidance, giving interested persons until October 4, 2002, to submit comments. After consideration of comments received, the draft guidance was changed in response to the comments and submitted to the VICH Steering Committee. At a meeting held on October 10 and 11, 2002, the VICH Steering Committee endorsed the final guidance for industry, VICH GL33.

Existing toxicological testing recommendations for veterinary drugs have evolved from the toxicological tests for human medicines, food additives, and pesticides. The following guidance was developed to include tests particularly relevant to the identification of a no-observable adverse effect level (NOAEL) for veterinary drugs. The scope of this guidance is to identify the following tests: (1) Basic tests recommended for all new animal drugs used in food-producing animals in order to assess the safety of drug residues present in human food; (2)