FOR FURTHER INFORMATION CONTACT: Naba K. Das, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1659.

SUPPLEMENTARY INFORMATION: The use of clorsulon suspension in goats is a new animal drug use under section 201(v) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(v)). As a new animal drug, clorsulon suspension is subject to section 512 of the act (21 U.S.C. 360b), which requires that its use in goats be the subject of an approved NADA or supplemental NADA. Goats are a minor specie under § 514.1(d)(1)(ii) (21 CFR 514.1(d)(1)(ii)).

The NRSP–7 Project, Southern Region, University of Florida, Gainesville, FL 32610, has filed data and information that demonstrate safety and effectiveness to goats orally drenched with a suspension containing 8.5 percent of clorsulon for the treatment of adult liver fluke (*Fasciola hepatica*) infestation. NRSP–7 has also filed human food safety data and an environmental assessment that adequately addresses the potential impacts due to use of the drug product.

The data and information are contained in PMF 5440. Sponsors of NADA's or supplemental NADA's may, without further authorization, refer to the PMF to support approval of an application filed under § 514.1(d). An NADA or supplemental NADA must include, in addition to reference to the PMF, animal drug labeling and other data needed for approval, such as manufacturing methods, facilities, and controls, and information addressing the potential environmental impacts (including occupational) of the manufacturing process. Persons desiring more information concerning the PMF or requirements for approval of an NADA may contact Naba K. Das (address above).

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of target animal safety, effectiveness, and human safety data and information provided in this PMF to support approval of an application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 6, 1997.

Michael J. Blackwell,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 97–1022 Filed 1–14–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96N–0478]

Cancer-Related Advisory Committees; Proposed Process for Selection of Patient Representatives

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting comments from interested parties on the proposed process for the selection of patient representatives to serve on cancer-related advisory committees. As part of the ''FDA Initiative on Reinventing the Regulation of Cancer Drugs,'' the Cancer Liaison Staff in the Office of AIDS and Special Health Issues has been charged with developing a process for recruitment, assessment, and selection of patient representatives to serve as members of cancer-related advisory committees in the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), and the Center for Devices and Radiological Health (CDRH). This initiative is intended to provide representation for cancer patients and to ensure that the selection process will provide for broad representation in the nominee pool, and to develop criteria for the selection of the patient representatives. The criteria for both the nomination and selection process will help ensure that the patient representative will provide the perspective of the patients with the disease for which a therapeutic product is being considered by the advisory committee.

DATES: Written comments on the proposed process by March 17, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: JoAnn Minor, Office of AIDS and Special Health Issues (HF–12), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4460 or E-mail: JMinor@bangate.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On March 29, 1996, President Clinton announced the ''FDA Initiative on Reinventing the Regulation of Cancer Drugs'' that will result in more rapid approval of cancer therapies and expanded access to investigational cancer therapies. This program of cancer initiatives also includes the participation of patient representatives on FDA advisory committees that review and consider cancer-related therapies. Advisory committees provide independent, outside expert scientific advice to the agency; they evaluate data concerning the safety and efficacy of products and make recommendations to the agency concerning their approval and appropriate use.

Patient representatives can provide a unique perspective during the deliberations of advisory committees. The patient representatives bring to the committee the views on the drug or product under review from individuals and families directly affected by the disease. The agency recognizes the valuable contributions that patient representatives provide. During the past several years, the Antiviral Drugs Advisory Committee and the Blood Products Advisory Committee have included patient representatives at their meetings when products for the treatment or diagnosis of human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS) and blood safety were under discussion. More recently, the Oncologic Drugs Advisory Committee, the Biological Response Modifiers Advisory Committee, and the Medical Imaging Drugs Advisory Committee have begun including such representatives.

Patients, patient advocacy groups, and others have endorsed the agency in its commitment to include patient representation on advisory committees. In the past, the medical review division and the advisory committee's Executive Secretary, acting upon recommendations by the Office of AIDS and Special Health Issues, selected patient representatives through an informal process. The agency believes that it would be useful to have a uniform system to recruit, select, and refer patient representatives to serve on FDA advisory committees. The following is a proposed process to formalize the recruitment and selection of patient representatives to serve on committees reviewing cancer-related therapies.

II. The Proposed Process

The agency is developing a process for the recruitment, assessment, selection, and training of patient representatives. As part of this process, the agency believes that a mechanism for soliciting nominations of qualified patient representatives to ensure broad representation in the nominee pool is critical. To that end, the agency proposes to develop: (1) A listing of qualifications to be considered in

selecting patient representatives, and (2) a plan for soliciting nominations.

A. Qualifications for Patient Representatives

The agency has decided that patient representatives on FDA advisory committees that review and consider cancer therapies will be voting members. Patient representatives will be subject to the same conflict of interest requirements as other committee members as set out in § 14.80 (21 CFR 14.80) and must serve as special Government employees. Section 14.80 defines the qualifications for voting members of advisory committees. FDA recognizes that in some cases the composition of an advisory committee is mandated by statute or regulation. The agency will make a determination to add a voting patient representative on a case-by-case basis when: (1) Meetings are planned; (2) FDA determines it is allowable within the statutes and regulations; and (3) it is feasible and beneficial to a committee's deliberation.

The primary role of the patient representative would be to provide to the advisory committee the perspective of the patients with the disease for which the therapeutic agent is being considered. Currently, many of the FDA advisory committees, including those that provide advice on cancer-related issues, include a representative who is broadly identified with consumer interests and who has been nominated and recommended by a consumer-oriented organization. However, because there are so many different cancers, the number of appropriate perspectives is larger than a single consumer can represent. To more specifically represent the interests of the patients, the FDA believes that a patient representative who understands issues specific to the cancer for which a drug, device, or biologic approval is being sought would bring valuable insights to the FDA advisory committee process. Multiple factors are important to determine the ability of a person to be an effective patient representative. In addition to the qualifications described under § 14.80, the following qualifications are under consideration for selecting patient representatives: (1) Personal experience with an illness, condition, or treatment; (2) experience as a patient advocate; (3) formal affiliation with a patient advocacy organization; (4) ability to articulate the perspective of the patient; (5) ability to identify issues through communications with patient constituencies; (6) ability to access mechanisms to disseminate information from an advisory committee meeting to the affected community; and (7) experience in technical issues before the committee.

B. Soliciting Nominations

The agency believes that a mechanism for soliciting nominations of qualified patient representatives to ensure broad representation in the nominee pool is critical. After the qualifications for voting patient representatives are defined, the agency proposes to solicit nominations by the following methods: (1) Federal Register announcement as set out in 21 CFR 14.82; and possibly through Internet announcements; (2) direct mailings of announcements and personalized letters to patient advocacy groups, community organizations, and other public interest organizations; (3) patient newsletter announcements; or (4) display announcements at conferences, advisory committee meetings, workshops, etc. that FDA staff members attend, and at other conferences, meetings, and workshops.

Nominations may be submitted by individuals, patient advocacy groups and organizations. Self nominations will also be acceptable.

III. Comments

FDA is seeking the views of the public with regard to the proposed qualifications that should be considered in selecting a patient representative and comments on the adequacy of the methods proposed to obtain nominations. The agency will review and consider written comments on the approach set forth in this notice. Any comments received will be considered in determining whether amendments to, or revisions of, the approach are warranted. Two copies of any comments should be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. Comments received are available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 30, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–945 Filed 1–14–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 97N–0002]

Policy on Period of Marketing Exclusivity for Newly Approved Drug Products With Enantiomer Active Ingredients; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is reevaluating its policy on the appropriate period of marketing exclusivity for newly approved drug products whose active ingredient is a single enantiomer of a previously approved racemate. This action is being taken to assess incentives for the development of new enantiomer drug products that may represent significant pharmaceutic advances. The agency is requesting comments on this issue and intends to publish a notice in Federal Register at a later date announcing its policy.

DATES: Written comments by March 17, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Wayne H. Mitchell, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1049.

SUPPLEMENTARY INFORMATION: FDA is requesting comments on the agency's policy on marketing exclusivity for drug products whose active ingredient is a single enantiomer of a previously approved racemate.

I. Enantiomers and Racemates

Stereoisomers are molecules that have the same constitution (i.e., molecular formula and chemical connectivity), but differ in the spatial orientation of the atoms. When two stereoisomers are mirror images, but are not superimposable upon each other (like left and right hands), they are referred to as enantiomers. Enantiomeric molecules are identical in all physical and chemical properties, except in an environment which is also chiral (characterized by handedness). Polarized light is such an environment, and pairs of enantiomers rotate the plane of polarization by equal amounts in opposite directions. Enantiomers may be either right-handed (dextro-rotary) S(+)-isomers or left-handed (levo-rotary) R(-)-isomers. Racemates are equimolar mixtures of enantiomers of the same molecule.