Substantial Evidence of Effectiveness of New Animal Drugs—21 CFR Part 514—(OMB Control No. 0910–0356)—Extension

Description: Congress enacted the Animal Drug Availability Act of 1996 (ADAA) (Public Law 104–250) on October 9, 1996. As directed by the ADAA, FDA published a final rule July 28, 1999 (64 FR 40746), amending part 514 (21 CFR part 514) to further define substantial evidence in a manner that encourages the submission of new animal drug applications (NADA's), supplemental NADA's and encourages dose range labeling. Substantial evidence is the standard that a sponsor must meet to demonstrate the effectiveness of a new animal drug for its intended uses under the conditions of use suggested in its proposed labeling. It is defined as evidence consisting of one or more adequate and well-controlled studies, such as a study in a target species, study in laboratory animals, field study, bioequivalence study, or an in vitro study, on the basis of which it could fairly and reasonably be concluded by qualified experts that the new animal drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof. The provisions of § 514.4(a) provide the agency with greater flexibility to make case-specific scientific determinations regarding the number and types of adequate and well-controlled studies that will provide, in an efficient manner, substantial evidence that a new animal drug is effective. The agency believes this regulation over time, will reduce the number of adequate and well-controlled studies necessary to demonstrate the effectiveness of certain combination new animal drugs, will eliminate the need for an adequate and well-controlled dose titration study, and may, in limited instances, reduce or eliminate the number of adequate and well-controlled field investigations necessary to demonstrate by substantial evidence the effectiveness of a new animal drug.

Description of Respondents: Respondents to this collection of information are persons and businesses, including small businesses. In the **Federal Register** of August 16, 2000 (65 FR 49989), the FDA published a 60-day notice concerning the proposed extension of this collection of information and requested comments. No comments were received on the estimated annual reporting burden. We therefore believe the total burden estimate of 544,036 hours for the annual reporting and recordkeeping burden should remain unchanged.

FDA estimates the burden of the 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
514.4(a)	190	4.5	860	632.6	544,036

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

The estimated annual reporting burden is based on consultation by the Center for Veterinary Medicine with several of the major research and development firms that conduct the majority of studies submitted to establish substantial evidence of effectiveness of new animal drugs and agency records.

Dated: November 9, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–29325 Filed 11–15–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Consumer Roundtable; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing the following meeting: Consumer roundtable to discuss consumer protection priorities for the agency. The roundtable will provide an opportunity for FDA to engage in an open dialogue with individual consumer stakeholders on a variety of regulatory and consumer oriented issues. The roundtable is part of the agency's ongoing consultation with stakeholders.

Date and Time: The meeting will be held on December 13, 2000, 9 a.m. to 4 p.m.

Location: The meeting will be held at the Penthouse Conference Room, Hubert H. Humphrey Bldg., 200 Independence Ave. SW., Washington, DC.

Contact: Karen R. Mahoney, Office of Consumer Affairs (HFE–88), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4393, FAX 301–827–2866, e-mail: *kmahoney@oc.fda.gov*.

Registration: Preregistration is required as space is limited. Send registration information (including name, title, organization name, address, telephone, fax number, and e-mail) to the contact person by December 6, 2000.

If you need special accommodations due to a disability, please contact Karen R. Mahoney (address above) at least 7 days in advance.

Background information on this meeting will be available on the FDA Internet site at *http://www.fda.gov/opacom/hpmeetings.html*.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

Dated: November 9, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Oncologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Oncologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.