releasable, and (2) enforcement actions which are releasable.

Three respondents were not clear whether approved product labeling was still required to accompany promotional materials, and one respondent proposed an alternative method of submitting labeling. The agency presently requests that sponsors submit two copies of the approved product labeling for each referenced drug product. This has been clarified on the form. Alternative methods of submitting approved product labeling may be considered at a later time.

Three respondents proposed that the agency provide the revised Form FDA 2253 in electronic form, and accept some promotional materials via electronic means. The agency currently provides many forms on the Internet using the World Wide Web (WWW) at ''http://www.fda.gov/opacom/morechoices/fdaforms/fdaforms.html'' and intends to add the revised Form FDA 2253 shortly after it is an approved form. As for the submission of promotional materials by electronic means, DDMAC is currently reviewing a pilot project where proposed promotional materials are submitted for review via CD–ROM and in hard copy. If successful, DDMAC plans to continue the pilot project and refine the means of submitting promotional materials by electronic means.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Form	No. of Respondents	Total Annual Responses	Hours per Response	Total Estimated Hours
FDA 2253	612	12,379	2	24,758

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

In fiscal year 1995, CDER received 10,879 submissions of advertising and promotional labeling under Form FDA 2253 from an estimated 512 manufacturers. In the same period of time, CBER received 1, 034 submissions from 57 manufacturers that could have made use of revised Form FDA 2253. Prior to October 7, 1997, the submission of advertising and promotional labeling to CBER using Form FDA 2567 was a voluntary procedure. Under § 601.12(f)(4) (62 FR 39890), manufacturers of licensed biological products are required to submit specimens of advertising and promotional labeling to FDA in accordance with § 314.81(b)(3)(i), FDA estimates that under the new regulation CBER will receive over 1,500 submissions from approximately 100 manufacturers that may use the revised Form FDA 2253. Thus, FDA estimates that there may be 12,379 submissions of advertising and promotional labeling to FDA under revised Form FDA 2253. Based on contacts with industry representatives, FDA estimates that 2 hours would be required for an industry regulatory affairs specialist to fill out the proposed form, collate the documentation, and send the submission to CDER or CBER. Manufacturers of biological products may use the revised Form FDA 2253 or may continue to use Form FDA 2567 for the submission of advertisements and promotional labeling to CBER.

Dated: June 2, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–15192 Filed 6–8–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0503]

Agency Information Collection Activities; Submission for OMB Review; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by July 9, 1998.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attention: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

New Animal Drug Application (NADA), Form FDA 356 V, 21 CFR Part 514—(OMB Control Number 0910–0032—Reinstatement)

Under the Federal Food, Drug, and Cosmetic Act (the act), FDA has the responsibility 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 a NADA before interstate marketing is allowed. The regulations implementing statutory requirements for NADA approval have been codified under 21 CFR part 514. NADA applicants generally use a single form, FDA 356 V. 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 a 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 for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Form No.	21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Form FDA 356 V	514.1 and 514.6	190	6.76	1,824	211.6	271,694
	514.8 and 514.9				30	8,520
	514.11				1	1,824
Total burden hours						282,038

[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 1996 data. The burden estimate includes original NADA's, supplemental NADA's, and amendments to unapproved applications.

Dated: June 2, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–15271 Filed 6–8–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Request for Nominations for Members on Public Advisory Committees; Veterinary Medicine Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for members to serve on the Veterinary Medicine Advisory Committee (the Committee) in FDA's Center for Veterinary Medicine.

FDA has a special interest in ensuring that women, minority groups, and the physically challenged are adequately represented on advisory committees and, therefore, extends particular encouragement to nominations for appropriately qualified candidates from these groups.

DATES: No cutoff date is established for receipt of nominations.

ADDRESSES: All nominations for membership should be submitted to Jacquelyn L. Pace (address below).

FOR FURTHER INFORMATION CONTACT: Jacquelyn L. Pace, Center for Veterinary Medicine (HFV–200), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6650.

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for members to serve on the Committee. The function of the Committee is to review and evaluate available data concerning safety and effectiveness of marketed and investigational new animal drugs, feeds, and devices for use in the treatment and prevention of animal disease and increased animal production.

Criteria for Members

Persons nominated for membership on the Committee shall have adequately diversified experience that is appropriate to the work of the Committee in such fields as companion animal medicine, food animal medicine, avian medicine, microbiology, biometrics, toxicology, pathology, pharmacology, animal science, public health/epidemiology, minor species/minor use veterinary medicine, and chemistry. The specialized training and experience necessary to qualify the nominee as an expert suitable for appointment is subject to review, but may include experience in medical practice, teaching, and/or research relevant to the field of activity of the Committee. The term of office is 4 years.

As of November 1, 1998, the Committee will have three vacancies in the areas of animal science, veterinary toxicology, and veterinary microbiology. However, membership nominations are not limited to these three areas.

Nomination Procedures

Any interested person may nominate one or more qualified persons for membership on the Committee. Nominations shall state that the nominee is willing to serve as a member of the Committee and appears to have no conflict of interest that would preclude committee membership. A current copy of the nominee's curriculum vitae should be included. Potential candidates will be asked by FDA to provide detailed information concerning such matters as employment, financial holdings, consultancies, and research grants or contracts in order to permit evaluation of possible sources of conflict of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: May 29, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–15195 Filed 6–8–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0374]

International Conference on Harmonisation; Draft Guidance on Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a draft guidance entitled ''Q6B Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products.'' The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guidance provides guidance on general principles for the selection of test procedures and the setting and justification of acceptance criteria for biotechnological and biological products. The draft guidance is intended to assist in the establishment of a uniform set of international specifications for biotechnological and biological products to support new marketing applications.

DATES: Written comments by July 24, 1998.

ADDRESSES: Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Copies of the draft guidance are available from the Drug Information Branch (HFD–210), Center for Drug