

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

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 514.6 514.8 and 514.9 514.11	190	6.76	1,824	211.6 30 1	271,694 8,520 1,824
Total burden hours						282,038

¹There 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]

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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]

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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