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: August 9, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–20720 Filed 8–15–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Request for Nominations for Nonvoting Members of Industry Interests on Public Advisory Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for nonvoting representatives of industry interests to serve on public advisory committees under the purview of the Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER). Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice announcing its intention of adding nonvoting industry representatives to certain public advisory committees.

FDA has a special interest in ensuring that women, minority groups, individuals with disabilities, and small businesses are adequately represented on advisory committees, and therefore, encourages nominations for appropriately qualified candidates from these groups. Specifically, in this document, nominations for nonvoting representatives of industry interests are encouraged from the biologics and/or drug manufacturing industry.

DATES: Nominations should be received by September 15, 2000.

ADDRESSES: All nominations for membership should be submitted to William Freas or John M. Treacy (addresses below).

FOR FURTHER INFORMATION CONTACT:

Regarding representatives of industry interests for CBER advisory committees: William Freas, Scientific Advisors and Consultants Staff (HFM–71), Food and Drug Administration, 5515 Rockville Pike, Rockville, MD 20852–1448, 301–827–0314.

Regarding representatives of industry interests for CDER advisory committees: John M. Treacy, Advisors and Consultants Staff (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001.

SUPPLEMENTARY INFORMATION: Section 120 of the FDA Modernization Act (FDAMA) of 1997 (21 U.S.C. 355) requires that newly formed FDA advisory committees include representatives from the biologics and/or drug manufacturing industries. Although not required for existing committees, to keep within the spirit of FDAMA, the agency intends to add nonvoting industry representatives to all its CBER and CDER advisory committees identified below.

I. Functions

A. Advisory Committees Under the Purview of CBER

1. Allergenic Products Advisory Committee

Reviews and evaluates available data concerning the safety, effectiveness, and adequacy of labeling of allergenic biological products or materials that are administered to humans for the diagnosis, prevention, or treatment of allergies and allergic disease.

2. Biological Response Modifiers Advisory Committee

Reviews and evaluates available data relating to the safety, effectiveness, and appropriate use of biological response modifiers which are intended for use in the prevention and treatment of a broad spectrum of human diseases.

3. Blood Products Advisory Committee [1]

Reviews and evaluates available data concerning the safety, effectiveness, and appropriate use of blood and products derived from blood and serum which are intended for use in the diagnosis, prevention, or treatment of human diseases.

4. Transmissible Spongiform Encephalopathies Advisory Committee

Reviews and evaluates available data concerning the safety of products which may be at risk for transmission of spongiform encephalopathies having an impact on the public health.

5. Vaccines and Related Biological Products Advisory Committee

Reviews and evaluates available data concerning the safety, effectiveness, and appropriate use of vaccines and related biological products intended for use in the diagnosis, prevention, or treatment of human diseases.

B. Advisory Committees Under the Purview of CDER

1. Advisory Committee for Pharmaceutical Science

Advises on scientific and technical issues concerning the safety and effectiveness of human generic drug products for use in the treatment of a broad spectrum of human diseases.

2. Advisory Committee for Reproductive Health Drugs

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in obstetrics, gynecology, and contraception.

3. Anesthetic and Life Support Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in anesthesiology and surgery.

4. Anti-Infective Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness

[1] Currently, there is a standing representative of industry interests on this advisory committee.

of marketed and investigational human drug products for use in the treatment of infectious diseases and disorders.

5. Antiviral Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of acquired immune deficiency syndrome (AIDS), HIV-related illnesses, and other viral, fungal, and mycobacterial infections.

6. Arthritis Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of arthritis, rheumatism, and related diseases.

7. Cardiovascular and Renal Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cardiovascular and renal disorders.

8. Dermatologic and Ophthalmic Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of dermatologic and ophthalmic disorders.

9. Drug Abuse Advisory Committee

Advises the Commissioner of Food and Drugs regarding the scientific and medical evaluation of all information gathered by the Department of Health and Human Services and the Department of Justice with regard to safety, efficacy, and abuse potential of drugs or other substances and recommends actions to be taken by the Food and Drug Administration with regard to marketing, investigation, and control of such drugs or other substances.

10. Endocrinologic and Metabolic Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of endocrine and metabolic disorders.

11. Gastrointestinal Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of gastrointestinal disorders.

12. Medical Imaging Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in diagnostic and therapeutic procedures using radioactive pharmaceuticals and contrast media used in diagnostic radiology.

13. Nonprescription Drugs Advisory Committee [1]

Reviews and evaluates available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products for use in the treatment of a broad spectrum of human symptoms and diseases.

14. Oncologic Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cancer.

15. Peripheral and Central Nervous System Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of neurologic disease.

16. Pharmacy Compounding Advisory Committee [1]

Provides advice on scientific, technical, and medical issues concerning drug compounding by licensed practitioners.

17. Psychopharmacologic Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the practice of psychiatry and related fields.

18. Pulmonary-Allergy Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of pulmonary disease and diseases with allergic and/or immunologic mechanisms.

II. Nomination Procedure

Any organization in the biologics and/or drug manufacturing industry wishing to participate in the selection of an appropriate industry representative of a particular advisory committee identified above, may nominate one or more qualified persons. Persons who nominate themselves as representatives of industry interests for a certain advisory committee may not participate in the overall selection process.

Nominees should be full-time employees of firms that manufacture products regulated by the agency or of consulting firms that represent biologics and/or drug manufacturers. Nomination packages should include a cover letter indicating the committee of interest and complete curriculum vitae of each nominee. The term of office is up to 4 years.

III. Selection Procedure

A letter will be sent to each party that has sent a nomination package to FDA for a particular advisory committee. The letter will provide the complete list of all nominees. It is the responsibility of each nominating organization to consult with one another to select a single member to represent the industry interests for the respective advisory committee. This must be completed within 60 calendar days upon receipt of the letter. If no individual is selected within the 60 calendar days, the Commissioner of Food and Drugs will select a nonvoting member to represent the industry interests for the respective advisory committee.

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: August 7, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

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[1] Currently, there is a standing representative of industry interests on this advisory committee.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committees; Industry Representation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its intention of adding one nonvoting representative of industry interests to the membership of its existing advisory committees that do not already have such nonvoting industry representation under the purview of the Center for Biologics Evaluation and Research