based on the labeling of an estimated 20,000 new and used AFVs each year at thirty-eight cents for each label (per industry sources), the annual AFV labeling cost is estimated to be $7,600. Estimated total annual non-labor cost burden associated with the Rule, therefore, would be $8,000 ($136.80 + $7,600.00), rounded to the nearest thousand.

Debra A. Valentine,

General Counsel.

[FR Doc. 00–20779 Filed 8–15–00; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1435]

Agency Information Collection Activities; Proposed Collection; Comment Request; Substantial Evidence of Effectiveness of New Animal Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension for an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting requirements necessary to meet the substantial evidence standard to demonstrate the safety and effectiveness of a new animal drug.

DATES: Submit written or electronic comments on the collection of information by October 16, 2000.

ADDRESSES: Submit electronic comments on the collection of information via the Internet at: http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm. Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Substantial Evidence of Effectiveness of New Animal Drugs—21 CFR Part 514 (OMB Control Number 0910–0356)—Extension

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 on 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, it will reduce the number of adequate and well-controlled studies necessary to demonstrate the effectiveness of certain combination new animal drugs, it will eliminate the need for an adequate and well-controlled dose titration study, and it 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.

Respondents to this collection of information are persons and businesses, including small businesses.

FDA estimates the burden of this 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: 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]

BILLING CODE 4160–01–F

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.