ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Financial Data Match Tape	4233	4	.5	8466
Election Form	241	1	.5	120.5
Estimated Total Annual Burden Hours				8586.5

In compliance with the requirements of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: March 14, 2001.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 01–6771 Filed 3–19–01; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0050]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Premarket Approval of Medical Devices; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of February 8, 2001 (66 FR 9582). The document announced an opportunity for public comment on a proposed collection of information; specifically, comments on the submission of premarket approval for a medical device. The notice published with one error. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In FR Doc. 01–3323, appearing on page 9582 in the **Federal Register** of Thursday, February 8, 2001, the following correction is made:

1. On page 9582, the title ''Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Classification/ Reclassification; Restricted Devices: Premarket Approval of Medical Devices'' is corrected to read ''Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Premarket Approval of Medical Devices.''

Dated: March 12, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 01–6777 Filed 3–19–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Biological Response Modifiers 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Biological Response Modifiers Advisory Committee.

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

Date and Time: The meeting will be held on April 5, 2001, from 9 a.m. to 6 p.m. and on April 6, 2001, from 8:30 a.m. to 3:30 p.m.

Location: Holiday Inn, Versailles I and II Ballroom.

Contact: Gail M. Dapolito (HFM–71), or Rosanna L. Harvey (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12389. Please call the Information Line for up-to-date information on this meeting.

Agenda: On April 5 and 6, 2001, the committee will meet to discuss: (1) Responses to the March 6, 2000, FDA Gene Therapy Letter (http://www.fda.gov/cber/letters.htm); (2) results of gene therapy clinical site inspections, (3) long-term follow-up of gene therapy patients, and (4) the FDA proposed rule entitled ''Availability for Public Disclosure and Submission to FDA for Public Disclosure of Certain Data and Information Related to Human Gene Therapy or Xenotransplantation'' (http://www.fda.gov/cber/rules.htm). In addition, the committee will receive an update on two research programs in the Division of Cellular and Gene Therapies and the Division of Monoclonal Antibodies, Center for Biologics Evaluation and Research.

Procedure: On April 5, 2001, from 9 a.m. to 5:15 p.m. and on April 6, 2001, from 8:30 a.m. to 3:30 p.m., the meeting is open to the public. Interested persons may present data, information or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by March 26, 2001. Oral presentations from the public will be scheduled between approximately 1:30

p.m. and 2 p.m. on April 5, 2001, and between approximately 11 a.m. to 11:30 a.m. on April 6, 2001. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 26, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On April 5, 2001, from 5:15 p.m. to 6 p.m. the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 5552b(c)(6)). The committee will discuss reports of the review of research programs in the Division of Cellular and Gene Therapies and the Division of Monoclonal Antibodies, Center for Biologics Evaluation and Research.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 12, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–6774 Filed 3–19–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants (Ranch Hand 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: Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants (Ranch Hand Advisory Committee).

General Function of the Committee: To advise the Secretary and the Assistant Secretary for Health concerning its oversight of the conduct of the Ranch Hand study by the U.S. Air Force and provide scientific oversight of the Department of Veterans Affairs (VA) Army Chemical Corps Vietnam Veterans Health Study, and other studies in which the Secretary or the Assistant Secretary for Health believes involvement by the committee is desirable.

Date and Time: The meeting will be held on April 5, 2001, 8:30 a.m. to 4:30 p.m.

Location: Parklawn Bldg., 5600 Fishers Lane, conference room B, third floor, Rockville, MD.

Contact: Leonard M. Schechtman, Food and Drug Administration, 5600 Fishers Lane, rm. 16–53, Rockville, MD 20857, 301–827–6696, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12560. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will review four research proposals and provide comments and recommendations to the U.S. Air Force. The proposals are concerned with measurements of: (1) Carotid intima-media thickness, (2) peripheral blood pressure, (3) nerve conduction velocity, and (4) archiving blood cells for future measurements of Ah receptor polymorphisms.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by March 26, 2001. Oral presentations from the public will be scheduled on April 5, 2001, between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 26, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 12, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–6776 Filed 3–19–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0049]

Guidance on Reduction of Civil Money Penalties for Small Entities; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing the final guidance entitled ''Reduction of Civil Money Penalties for Small Entities'' as required by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) and the Presidential Memorandum of April 21, 1995.

DATES: The final guidance is effective April 19, 2001. Written comments may be submitted at any time.

ADDRESSES: Submit written comments on the final guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. Submit written requests for single copies of the final guidance to the Division of Compliance Policy (HFC–230), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or fax your request to 301–827–0482. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the final guidance.

FOR FURTHER INFORMATION CONTACT: Jeffrey B. Governale, Division of Compliance Policy (HFC–230), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0411, FAX 301–827–0482.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is issuing a final guidance for the reduction of civil money penalties (CMP's) for small entities (penalty reduction guidance) as mandated by SBREFA (Public Law 104–121) and the Presidential Memorandum of April 21, 1995 (60 FR 20621, April 26, 1995). SBREFA was enacted on March 29, 1996, and seeks to improve the regulatory climate for small entities by, among other things, requiring agencies to establish small entity penalty reduction policies. The Presidential Memorandum of April 21, 1995, directs agencies to use their discretion to