DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0290]

Compounding of Drugs for Use in Animals Compliance Policy Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration is announcing the availability of a compliance policy guide (CPG) for FDA staff and industry entitled ''Sec. 608.400 - Compounding of Drugs for Use in Animals,'' which provides guidance on how FDA intends to address compounding of animal drugs.

DATES: Submit written or electronic comments at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Director, Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request or fax your request to 301–827–0482. Submit written comments on the CPG to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the document.

FOR FURTHER INFORMATION CONTACT: Neal Bataller, Center for Veterinary Medicine (HFV–230), Food and Drug Administration, 7500 Standish Pl., rm. E441, Rockville, MD 20855, 301–827–0163, e-mail: *nbatalle@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On July 3, 1996, FDA issued a CPG section 608.400 ''Compounding of Drugs for Use in Animals,'' which provided guidance to FDA's field and headquarters staff with regard to the compounding of drugs for use in animals by veterinarians and pharmacists. It described the factors FDA intended to consider in exercising its enforcement discretion regarding the illegal compounding of drugs intended for use in animals.

FDA is updating this CPG to ensure that its enforcement policy regarding the compounding of drugs intended for use in animals is consistent, to the extent practicable, with its enforcement policy regarding the compounding of drugs intended for use in humans. FDA issued the latter enforcement policy entitled ''Pharmacy Compounding Compliance Policy Guide'' that published in the **Federal Register** of June 7, 2002 (67 FR 39409). FDA issued this CPG after the U.S. Supreme Court ruled that a statutory provision governing the compounding of drugs intended for human use was unconstitutional. Because of that court decision, FDA determined that it needed to issue guidance to the compounding industry on what types of compounding might be subject to enforcement action under current law. The guidance was based in part on an earlier CPG.

In addition to ensuring that its policies regarding the compounding of drugs intended for use in humans and animals are consistent, FDA is revising its previous animal drug compounding CPG to ensure it is consistent with the current animal drug compounding regulations, which are codified at 21 CFR part 530.

II. Significance of Guidance

This compliance policy guidance is being issued as a level 1 guidance consistent with FDA's good guidance practices (GGPs) regulation in § 10.115 (21 CFR 10.115). It is being implemented immediately without prior public comment, under § 10.115(g)(2), because of the agency's urgent need to explain how, in light of the recent court decision and revised policy regarding drugs for human use, it intends to exercise its enforcement discretion regarding compounded drugs for animal use. However, under GGPs, FDA requests comments on the guidance and will revise the document, if appropriate. Comments will be considered by the agency in the development of future policy.

This compliance policy guidance represents the agency's current thinking on the enforcement of the act with regard to drug products compounded for use in animals. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statutes and regulations.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the CPG at any time. Two paper copies of any mailed comments are to be submitted, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the CPG and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain copies of the CPG at FDA's Office of Regulatory Affairs Web site at *http://www.fda.gov/ora* under ''Compliance References.''

Dated: July 8, 2003.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 03–17758 Filed 7–11–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Proposed Collection; Comment Request, the Athersoclerosis Risk in Communities Study (ARIC)

SUMMARY: In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: The Atherosclerosis Risk in Communities Study (ARIC).*Type of Information Collection Request:* Revision of a currently approved collection (OMB No. 0925–0281). *Need and Use of Information Collection:* This project involves annual follow-up by telephone of participants in the ARIC study, review of their medical records, and interviews with doctors and family to identify disease occurrence. Interviewers will contact doctors and hospitals to ascertain participants' cardiovascular events. Information gathered will be used to further describe the risk factors, occurrence rates, and consequences of cardiovascular disease in middle aged and older men and women. *Frequency of Response:* The participants will be contacted annually. *Affected Public:* Individuals or households; Businesses or other for profit; Small businesses or

organizations. *Type of Respondents:* Individuals or households; doctors and staff of hospitals and nursing homes.

The annual reporting burden is as follows: *Estimated Number of Respondents:* 15,113; *Estimated Number of Responses per Respondent:* 1.0; *Average Burden Hours Per Response:* 0.2479; and *Estimated Total Annual Burden Hours Requested:* 3,746. The annualized cost to respondents is estiamted at $41,453, assuming respondents time at the rate of $10 per hour and physician time at the rate of $75 per hour. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

ESTIMATE OF ANNUAL HOUR BURDEN

Type of Response	Number of respondents	Frequency of response	Average time per response	Annual hour burden
Participant Follow-up	14,488	1.0	0.2500	3,622
Physician, hospital, nursing home staff [1]	245	1.0	0.2500	61
Participant's next-of-kin [1]	380	1.0	0.1667	63
Total	15,113	1.0	0.2479	3,746

[1] Annual burden is placed on doctors, hospitals, nursing homes, and respondents relatives/informants through requests for information which will hep in the compilation of the number and nature of new fatal and nonfatal events.

Request for Comments

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performanace of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency'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 those who are to respond, including the use of appropriate atomated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. Paul Sorlie, Project Officer, National Institutes of Health, NHLBI, 6701 Rockledge Drive, MSC 7934, Bethesda, MD 20892–7934, or call non-toll-free number (301) 435–0456 or e-mail your request, including your address to: *SorlieP@nhlbi.nih.gov.*

Comments Due Date

Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of publication.

Dated: July 3, 2003.

Peter Savage,

Director, Division of Epidemiology and Clinical Applications.

[FR Doc. 03–17649 Filed 7–11–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meeting

Pursuant to section 10(d) to the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Eye Institute Special Emphasis Panel, PEDIG.

Date: July 23, 2003.

Time: 1 p.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6120 Executive Blvd., Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Jeanette M. Hosseini, PhD, Scientific Review Administrator, Division of Extramural Research, National Eye Institute, Bethesda, MD, 20892, (301) 451–2020.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: July 7, 2003.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–17643 Filed 7–11–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel, 03–78, Review of R13s

Date: August 7, 2003.

Time: 10 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: H. George Hausch, PhD, Acting Director, 4500 Center Drive, Natcher Building, Rm. 4AN44F, National Institutes of Health, Bethesda, MD 20892, (301) 594–2372, *george_hausch@nih.gov.*