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The Director, Management Analysis and Services office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: April 28, 2003.

**Alvin Hall,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 03-10974 Filed 5-2-03; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Notice of Correction

In the **Federal Register** of April 10, 2003, Volume 68, Number 69, Page 17654 the following should read as follows:

#### Correction

*Name:* Board of Scientific Counselors, National Center for Infectious Diseases: Meeting.

*Time and Date:* 8:30 a.m.-3:30 p.m., May 2, 2003.

*Place:* CDC, Auditorium B, Building 1, 1600 Clifton Road, Atlanta, Georgia 30333.

Due to programmatic issues the corrected **Federal Register** notice is being published less than fifteen days before the meeting.

*Contact Person for More Information:* Tony Johnson, Office of the Director, NCID, CDC, Mailstop E-51, 1600 Clifton Road, NE., Atlanta, Georgia 30333, e-mail [tjohnson3@cdc.gov](mailto:tjohnson3@cdc.gov); telephone 404/498-3249.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: April 29, 2003.

**Alvin Hall,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Advisory Board on Radiation and Worker Health: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting:

*Name:* Advisory Board on Radiation and Worker Health (ABRWH), National Institute for Occupational Safety and Health (NIOSH).

*Time and Date:* 8 a.m.—5 p.m., May 19, 2003. 8 a.m.—2 p.m., May 20, 2003.

*Place:* Garden Plaza Hotel, 215 South Illinois Avenue, Oak Ridge, Tennessee 37830, telephone (865) 481-2468, fax (865) 481-2474.

*Status:* Open to the public, limited only by the space available. The meeting room accommodates approximately 65 people.

*Background:* The Advisory Board on Radiation and Worker Health ("the Board") was established under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) of 2000 to advise the President, through the Secretary of Health and Human Services (HHS), on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Board include providing advice on the development of probability of causation guidelines which have been promulgated by HHS as a final rule, advice on methods of dose reconstruction which have also been promulgated by HHS as a final rule, evaluation of the scientific validity and quality of dose reconstructions conducted by NIOSH for qualified cancer claimants, and advice on the addition of classes of workers to the Special Exposure Cohort.

In December 2000, the President delegated responsibility for funding, staffing, and operating the Board to HHS, which subsequently delegated this authority to the CDC. NIOSH implements this responsibility for CDC. The charter was signed on August 3, 2001, and the President has completed the appointment of members to the Board to ensure a balanced representation on the Board.

*Purpose:* This board is charged with (a) providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this Program; and (c) upon request by the Secretary, HHS, advise the Secretary on whether there is a class of employees at any Department of Energy (DOE) facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class.

*Matters to be Discussed:* The agenda for this meeting will focus on the Program Status

Report; NIOSH-IREP v5.2.1; United Kingdom Compensation Scheme for Radiation Linked Diseases; Workgroup Report on Dose Reconstruction Review Process; Future consideration on uncertainty in Interactive RadioEpidemiology Program (IREP); a refresher and update on Radiation Effectiveness Factors (REFs) assumed in IREP; a status report on epidemiologic studies of DOE workers; and, a presentation on FACA, Membership and Ethics.

Agenda items are subject to change as priorities dictate.

*Contact Person for more Information:* Larry Elliott, Executive Secretary, ABRWH, NIOSH, CDC, 4676 Columbia Parkway, Cincinnati, Ohio 45226, telephone (513) 841-4498, fax (513) 458-7125.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: April 28, 2003.

**Alvin Hall,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 03-10975 Filed 5-2-03; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 88N-0038]

#### Agency Information Collection Activities; Submission for OMB Review; Comment Request; Records and Reports Concerning Experience With Approved New Animal Drugs

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written or electronic comments on the collection of information by June 4, 2003.

**ADDRESSES:** The Office of Management and Budget (OMB) is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be electronically mailed to

sshapiro@omb.eop.gov or faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Stuart Shapiro, Desk Officer for FDA, FAX 202-395-6974.

**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:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Records and Reports Concerning Experience With Approved New Animal Drugs— (OMB Control Number 0910-0284)**

*Description:* This final rule amends the provisions of the animal drug regulations concerning requirements for recordkeeping and reports concerning experience with approved new animal drugs. The information contained in the reports required by this rule enables FDA to monitor the use of new animal drugs after approval and to ensure their continued safety and efficacy. The reporting requirements include: (1) A report that provides information on product and manufacturing defects that may result in serious adverse drug events within 3 days of becoming aware the defect exists (§ 514.80(b)(1) (21 CFR 514.80(b)(1))); (2) a report that provides information on serious and unexpected adverse drug events and a followup report on such events (§ 514.80(b)(2)); (3) a summary report of increased frequency of adverse drug experiences (§ 514.80(b)(4)(v)); (4) a report from nonapplicants, such as distributors, to applicants providing information on adverse drug experiences (§ 514.80(b)(3)); (5) a periodic report with information on distribution, labeling, manufacturing or controls changes, new laboratory studies, and all adverse events in the reporting period (§ 514.80(b)(4)); (6) other reports that

include special drug experience reports; and (7) reports for advertising and promotional labeling, and reports for distributor statements (§ 514.80(b)(5)). These reports must be kept for 5 years (§ 514.80(e)).

The final rule strengthens the current reporting system by requiring periodic reports every 6 months for the first 2 years following initial approval of an application rather than just for the first year following initial approval. The increased burden on applicants amounts to one additional periodic report. While greater than the reporting burden in the previous rule, this burden is less than that of the proposed rule which would have required quarterly periodic reports for 3 years following initial approval.

All periodic reports must be submitted with Form FDA 2301, "Transmittal of Periodic Reports and Promotional Materials for New Animal Drugs" (OMB control number 0910-0012). Adverse drug experience reports must be submitted on Form FDA 1932, "Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report" (OMB control number 0910-0012).

In the **Federal Register** of February 4, 2002 (67 FR 5046), FDA invited comments on the interim final rule and the information collection requirements. Only one comment received pertained to information collection. That comment stated that the requirements under "Multiple Applications" do not appear to decrease but may increase the burden on the applicant. In particular, the comment questioned the requirement under § 514.80(c)(4) and requested clarification. The comment also voiced concern about an increased reporting burden due to the increasing number of approved applications for combinations of drugs for use in feeds since the implementation of the Animal Drug Availability Act of 1996. Further complicating the reporting issue is that frequently there are nonapplicants involved in the marketing of these combinations. The comment stated that

with the exception of "promotion literature," there is rarely any other information to be reported, suggesting that the "promotion literature" be submitted to the application held by either party, i.e., the nonapplicants or applicant, and not the application approved for the use of the combination of drugs.

In response, FDA notes that the provision of the regulation in question is currently codified under § 510.300(b)(4)(ii). The current regulation and the proposal in the interim final rule are similar. There is no increase of the reporting burden. It is not the intention of FDA for the implementation of § 514.80(c) to be different from the current requirement under § 510.300(b)(4)(ii). There is no additional reporting burden than that already covered under § 514.80(b)(4). Section 514.80(c) is not an additional information collection, i.e., in addition to § 514.80(b)(4); it is an administrative tool for industry to use to submit common information only once to FDA. Only information specific to a particular new animal drug application (NADA)/ abbreviated new animal drug application (ANADA) that is not common to all the applications must be included in the report for that particular NADA/ANADA; for example, labeling. With regard to the comment that there is an increased reporting burden due to the Animal Drug Availability Act of 1996, increased reporting is due to the increased number of approved applications. FDA consequently believes that this is a reasonable reporting requirement.

*Description of Respondents:* Applicant respondents are sponsors of approved NADAs and ANADAs. Nonapplicant respondents are those, other than the applicant, involved in manufacturing, processing, packing, labeling, or distributing new animal drugs.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section/Title/FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
514.80(b)(2)(i)/Original 15-day Alert Report/Form FDA 1932	190	55.26	12,283	1	12,283
514.80(b)(1)/3-day Field Alert Report/Form FDA 1932	190	0.32	95	1	95
514.80(b)(2)(ii)/Followup 15-day Alert Report/Form FDA 1932	190	17.90	6,007	1	6,007
514.80(b)(3)/Nonapplicant Report/Form FDA 1932	340	2.94	1,000	1	1,000
514.80(b)(4)/Periodic Drug Experience Report/Form FDA 2301, and 514.80(c) Multiple Applications <sup>2</sup>	190	7.11	1,226	11	13,486

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>—Continued

21 CFR Section/Title/FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
514.80(b)(4)(v)/Summary Report of Increased Frequency of Adverse Drug Experience	190	1.58	300	2	600
514.80(b)(5)(i)/Special Drug Experience Report/Form FDA 2301	190	0.13	25	2	50
514.80(b)(5)(ii)/Advertising and Promotional Materials Report/Form FDA 2301	190	2.11	772	2	1,544
514.80(b)(5)(iii)/Distributor's Statement Report/Form FDA 2301	530	0.14	56	2	112
Total					35,177

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> The reporting burden for § 514.80(b)(4)(iv)(A) is included in the reporting burden for § 514.80(b)(2)(i).

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency of Response	Total Annual Responses	Hours per Response	Total Hours
514.80(e) <sup>2</sup>	530	28.22	19,385	0.5	9,693
514.80(e) <sup>3</sup>	530	4.06	2,379	10.35	24,623
Total					34,316

<sup>1</sup> Burden estimates were separated between Form FDA 1932 and Form FDA 2301 to reflect the difference in estimates for "Hours per Respondent" required.

<sup>2</sup> Recordkeeping estimates for § 514.80(b)(1), (b)(2)(i), (b)(2)(ii), and (b)(3); Form FDA 1932.

<sup>3</sup> Recordkeeping estimates for § 514.80(b)(2)(iii), (b)(4), (b)(5), and (c); Form FDA 2301.

Forms FDA 1932 and FDA 2301 for this collection of information are currently approved under OMB control number 0910-0012 and will not change due to implementation of this regulation. The reporting and recordkeeping burden estimates in this document are based on the submission of reports to the Division of Surveillance, Center for Veterinary Medicine. The total annual response numbers are based on the 2000 fiscal year submission of reports to the Division of Surveillance, Center for Veterinary Medicine. The numbers in tables 1 and 2 of this document are total burden associated with this regulation. Section 514.80(b)(3) and (b)(4)(v) are new information collection requirements over the current requirements.

Dated: April 28, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 03-10932 Filed 5-2-03; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICE

### Health Resources and Services Administration

#### HRSA-03-099 Fiscal Year 2003 Competitive Cycle for the Bioterrorism Training and Curriculum Development Program (BTCDP) 93.996

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Health Resources and Services Administration announces that cooperative agreement applications will be accepted for the Bioterrorism Training and Curriculum Development Program for Fiscal Year 2003.

*Purpose:* The Bioterrorism Training and Curriculum Development Program consists of two discrete goals: (1) Provision of Continuing Education for practicing providers; and (2) Curricular Enhancement in health professions schools. Each area requires a separate application for funds.

Cooperative Agreements will be awarded to assist eligible entities to prepare a workforce of healthcare professionals to address the medical consequences of bioterrorism and other public health emergency preparedness and response issues. In this context, "other public health emergencies" includes other forms of terrorism (such as use of chemical, explosive,

incendiary, or nuclear agents against the civilian population) as well as natural disasters and catastrophic accidents. Specifically, the goal of this program is the development of a healthcare workforce that possesses the knowledge, skills and abilities to: (1) Recognize indications of a terrorist event; (2) meet the acute care needs of patients, including pediatric and other vulnerable populations, in a safe and appropriate manner; (3) participate in a coordinated, multidisciplinary response to terrorist events and other public health emergencies; and (4) rapidly and effectively alert the public health system of such an event at the community, State, and national level.

Healthcare professionals provide a pivotal link to their communities. They disseminate accurate, responsible, trustworthy, and timely health related information to the public-at-large. This crucial component of the emergency response network helps to mitigate mortality and morbidity and to preserve public order while using resources effectively and efficiently. These professionals must be provided with the essential information needed to quickly identify a terrorist event; appropriately treat/respond to those in need of acute care; rapidly report such events to the public health authorities at the local, State and national levels, and participate in a coordinated and multidisciplinary response. The ability to meet the population's needs for acute