

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. 95N-0346]

Akorn, Inc., et al.; Withdrawal of Approval of NADA's**AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.**SUMMARY:** The Food and Drug Administration (FDA) is withdrawing

approval of five new animal drug applications (NADA's). Three NADA's are held by Akorn, Inc., and one each is held by Parke-Davis, Division of Warner-Lambert Co., and Veterinary Research and Development, Inc. The firms notified the agency in writing that the animal drug products were no longer marketed and requested that approval of the applications be withdrawn. In a final rule published elsewhere in this issue of the Federal Register, FDA is amending the regulations by removing the entries which reflect approval of the NADA's.

EFFECTIVE DATE: December 22, 1995.

FOR FURTHER INFORMATION CONTACT: Mohammad I. Sharar, Center for Veterinary Medicine (HFV-216), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0159.

SUPPLEMENTARY INFORMATION: The sponsors of the applications listed in the table in this document have informed FDA that these animal drug products are no longer marketed and have requested that FDA withdraw approval of the applications.

NADA No.	Drug name	Sponsor name and address
6-032	Diphenylhydantoin sodium capsules	Parke-Davis, Division of Warner-Lambert Co., 201 Tabor Rd., Morris Plains, NJ 07950
12-444	Sterile prednisolone suspension	Akorn, Inc., 100 Akorn Dr., Abita Springs, LA 70420
94-978	Phenylbutazone injection	Do.
110-046	Dexamethasone injection	Do.
140-904	Copper disodium edetate injection	Veterinary Research and Development, Inc., P.O. Box 1299, Truckee, CA 95734

Therefore, under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Veterinary Medicine (21 CFR 5.84), and in accordance with § 514.115 *Withdrawal of approval of applications* (21 CFR 514.115), notice is given that approval of NADA's 6-032, 12-444, 94-978, 110-046, and 140-904 and all supplements and amendments thereto is hereby withdrawn, effective December 22, 1995.

In a final rule published elsewhere in this issue of the Federal Register, FDA is removing 21 CFR 520.704, 522.514, and 522.1880, and amending 21 CFR 510.600(c), 522.540, and 522.1720 to reflect the withdrawal of approval of the above mentioned NADA's.

Dated: December 4, 1995.

Stephen F. Sundlof,
Director, Center for Veterinary Medicine.
[FR Doc. 95-30122 Filed 12-11-95; 8:45 am]
BILLING CODE 4160-01-F

[Docket No. 95D-0370]

Revised Compliance Policy Guides (CPG's); Availability**AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revision of two CPG's. The CPG's are being revised because they contain outdated information and misprinted regulatory guidance. This action is being

taken to ensure that FDA's CPG's accurately reflect FDA policy and to limit confusion.

DATES: Effective December 12, 1995. Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of CPG Sec. 545.400 "Pottery (Ceramics); Imported and Domestic—Cadmium Contamination" (CPG 7117.06), and CPG Sec. 545.450 "Pottery (Ceramics); Imported and Domestic—Lead Contamination" (CPG 7117.07) to the Director, Division of Compliance Policy (HFC-230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on CPG Sec. 545.400 "Pottery (Ceramics); Imported and Domestic—Cadmium Contamination" (CPG 7117.06) and CPG Sec. 545.450 "Pottery (Ceramics); Imported and Domestic—Lead Contamination" (CPG 7117.07) to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville MD, 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of CPG Sec. 545.400 "Pottery (Ceramics); Imported and Domestic—Cadmium Contamination" (CPG 7117.06) and CPG Sec. 545.450 "Pottery (Ceramics); Imported and Domestic—Lead Contamination" (CPG 7117.07) and

received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Ronald C. Varsaci, Center for Food Safety and Applied Nutrition (HFS-022), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4251.

SUPPLEMENTARY INFORMATION: FDA is revising the following two CPG's because they contain outdated information or misprinted regulatory guidance: (1) CPG Sec. 545.400 "Pottery (Ceramics); Imported and Domestic—Cadmium Contamination" (CPG 7117.06), and (2) CPG Sec. 545.450 "Pottery (Ceramics); Imported and Domestic—Lead Contamination" (CPG 7117.07).

The guidance for flatware and small hollowware in CPG Sec. 545.400 and for pitchers in CPG Sec. 545.450 was mistakenly printed as 0.05 instead of 0.5 microgram/milliliter. The CPG's are also being revised to specify current methodologies in the Official Methods of Analysis of the Association of Official Analytical Chemists International (AOAC) and to include the American Society for Testing Materials (ASTM) and Laboratory Information Bulletin (LIB) methodologies. The CPG provides guidance on recommending legal actions and on when entries of potteries should be detained based on cadmium or lead contamination. To minimize any confusion that may exist, FDA has decided to issue revisions.

Dated: December 5, 1995.

Gary Dykstra,

*Acting Associate Commissioner for
Regulatory Affairs.*

[FR Doc. 95-30171 Filed 12-11-95; 8:45 am]

BILLING CODE 4160-01-F

National Institutes of Health

National Institute of Dental Research; Notice of Closed Meeting

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 National Institute of Dental Research Special Emphasis Panel (SEP) meetings:

Name of SEP: National Institute of Dental Research Special Emphasis Panel-Review of R03 Small Grants—96-05 (Teleconference).

Dates: December 13, 1995.

Time: 1 pm.

Place: Natcher Building, Rm. 4AN-44F, National Institutes of Health, Bethesda, MD 20892.

Contact Person: Dr. William Gartland, Scientific Review Administrator, 4500 Center Drive, Natcher Building, Room 4AN-44F, Bethesda, MD 20892, (301) 594-2372.

Purpose/Agenda: To evaluate and review grant applications and/or contract proposals.

Name of SEP: National Institute of Dental Research Special Emphasis Panel-Review of Research Projects, Small Business Grants, and Conference Grants—96-06.

Dates: December 14, 1995.

Time: 8 am.

Place: Bethesda Marriott Hotel, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Dr. George Hausch, Chief, Grants Review Section, 4500 Center Drive, Natcher Building, Room 4AN-44F, Bethesda, MD 20892, (301) 594-2372.

Purpose/Agenda: To evaluate and review grant applications and/or contract proposals.

This notice is being published less than fifteen days prior to the above meetings due to the urgent need to meet timing limitations imposed by the review and funding cycle.

Name of SEP: National Institute of Dental Research Special, Emphasis Panel-Review of Oral Cancer Centers—96-07.

Dates: January 7-11, 1996.

Time: 8 am.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD 20814.

Contact Person: Dr. Yong Shin, Scientific Review Administrator, 4500 Center Drive, Natcher Building, Room 4AN-44F, Bethesda, MD 20892, (301) 594-2372.

Purpose/Agenda: To evaluate and review grant applications and/or contract proposals.

Name of SEP: National Institute of Dental Research Special Emphasis Panel-Review of the Conference Grants—97-10 (Teleconference).

Dates: January 18, 1996.

Time: 11 am.

Place: Natcher Building, Rm. 4AN-44F, National Institutes of Health, Bethesda, MD 20802.

Contact Person: Dr. George Hausch, Chief, Grants Review Section, 4500 Center Drive, Natcher Building, Room 4AN-44F, Bethesda, MD 20892, (301) 594-2372.

Purpose/Agenda: To evaluate and review grant applications and/or contract proposals.

Name of SEP: National Institute of Dental Research Special Emphasis Panel-Review of Coop Agreement Applications—96-08.

Dates: January 23-24, 1996.

Time: 8 am.

Place: Bethesda Marriott Hotel, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Dr. Philip Washko, Scientific Review Administrator, 4500 Center Drive, Natcher Building, Room 4AN-44F, Bethesda, MD 20892, (301) 594-2372.

Purpose/Agenda: To evaluate and review grant applications and/or contract proposals.

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

(Catalog of Federal Domestic Assistance Program No. 93.121, Oral Diseases and Disorders Research)

Dated: December 7, 1995.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 95-30303 Filed 12-11-95; 8:45 am]

BILLING CODE 4140-01-M

Division of Research Grants; 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 Division of Research Grants Special Emphasis Panel (SEP) meetings.

Purpose/Agenda: To review individual grant applications.

Name of SEP: Clinical Sciences.

Date: December 12, 1995.

Time: 5:15 p.m.

Place: NIH, Rockledge 2, Room 4104, Telephone Conference.

Contact Person: Dr. Priscilla Chen, Scientific Review Administrator, 6701 Rockledge Drive, Room 4104, Bethesda, Maryland 20892, (301) 435-1787.

Name of SEP: Biological and Physiological Sciences.

Date: December 13, 1995.

Time: 4 p.m.

Place: NIH, Rockledge 2, Room 4148, Telephone Conference.

Contact Person: Dr. Philip L. Perkins, Scientific Review Administrator, 6701 Rockledge Drive, Room 4148, Bethesda, Maryland 20892, (301) 435-1787.

This notice is being published less than 15 days prior to the above meetings due to the urgent need to meet timing limitations imposed by the grant review and funding cycle.

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

(Catalog of Federal Domestic Assistance Program Nos. 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes, of Health, HHS).

Dated: December 6, 1995.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 95-30304 Filed 12-11-95; 8:45 am]

BILLING CODE 4140-01-M

Substance Abuse and Mental Health Services Administration

Office for Women's Services; Notice of Meeting

Pursuant to Public Law 92-463, notice is hereby given of the meeting of the Advisory Committee for Women's Services of the Substance Abuse and Mental Health Services Administration (SAMHSA) in January 1996.

The meeting of the Advisory Committee for Women's Services will include a discussion of and update on policy and program issues relating to women's substance abuse and mental health service needs at SAMHSA, including the SAMHSA fiscal year 1996 budget and reauthorization; regional meetings on SAMHSA's proposed Performance Partnership Grants; SAMHSA policy on inclusion and attention to the needs of women and racial/ethnic minority populations; activities of the National Women's Resource Center for the Prevention and Treatment of Alcohol, Tobacco and Other Drug Abuse and Mental Illness; monitoring the impact of change at HHS; and a discussion of data collection pertaining to women.

A summary of the meeting and/or a roster of committee members may be obtained from: Pamela J. McDonnell,