

that compared to conventional, ethylene glycol-based antifreeze ("EG antifreeze"), Sierra and other PG antifreezes are safer for the environment generally. According to the complaint, although respondents had a reasonable basis that Sierra and other PG antifreezes, compared to EG antifreeze, are less toxic, and therefore safer for that part of the environment that is composed of humans, pets, and wildlife that may accidentally ingest it, respondents did not substantiate their claim that Sierra and other PG antifreezes are safer for the environment generally (e.g., the air, water, soil, plants, or aquatic life). The complaint also alleges that respondents represented without adequate substantiation that Sierra and other PG antifreezes are absolutely safe for the environment after ordinary use and that because Sierra and other PG antifreezes are biodegradable, they are absolutely safe for the environment after ordinary use. The complaint states that one reason these claims are unsubstantiated is that used antifreeze, whether EG or PG-based, may contain lead and/or other substances that are hazardous to the environment.

Furthermore, the complaint charges that the respondents represented without adequate substantiation that Sierra and other PG antifreezes are absolutely safe for people and pets. The complaint also charges that respondents claimed without adequate substantiation that because Sierra and other PG antifreezes contain PG—an ingredient designated by the Food and Drug Administration as "generally recognized as safe" and which is found in foods, drugs, cosmetics, and pet foods—they are absolutely safe for people and pets. According to the complaint, although respondents had a reasonable basis that Sierra and other PG antifreezes are safer than EG antifreeze, respondents lacked substantiation for the claim that they are absolutely safe.

In addition, the complaint alleges that the respondents made the unsubstantiated representation that compared to conventional, EG antifreeze, Sierra provides superior automotive protection from freezing temperatures, boil-overs, and corrosion.

Finally, the complaint charges that the respondents falsely and without adequate substantiation represented that Sierra antifreeze and its plastic container are recyclable. In fact, the complaint alleges, while both Sierra and its container are capable of being recycled, the vast majority of consumers cannot recycle either of them because there are few collection facilities

nationwide that accept PG antifreeze or high-density polyethylene plastic antifreeze containers for recycling.

The proposed consent order contains provisions designed to remedy the violations charged and to prevent the respondents from engaging in similar acts and practices in the future.

Part I of the proposed order requires the respondents to cease and desist from representing that any antifreeze, coolant, or deicer product will not harm the environment, is less harmful to the environment than other products, or offers any environmental benefit, unless the respondents possess competent and reliable evidence, which when appropriate must be competent and reliable scientific evidence, that substantiates the representation.

Part II of the proposed order requires the respondents to cease and desist from making any representation about the safety or relative safety for humans or animals of any antifreeze, coolant, or deicer product, unless they possess competent and reliable scientific evidence that substantiates the representation.

Part III of the proposed order requires that the respondents print the following two statements on the back of containers of all PG antifreeze or coolant products: "CAUTIONARY INFORMATION: This Product MAY BE HARMFUL IF SWALLOWED. STORE SAFELY AWAY FROM CHILDREN AND PETS. Do not store in open or unlabeled containers" and "Clean up any leaks or spills." On the front of all such containers the following must be disclosed: "See Back Panel for CAUTIONARY INFORMATION." Part III also specifies the manner in which these disclosures must be made.

Part IV of the proposed order requires the respondents to cease and desist from making any representation about the level of vehicular engine protection provided by any antifreeze, coolant, or deicer product, unless the respondents possess competent and reliable scientific evidence that substantiates the representation.

Part V of the proposed order requires that the respondents cease and desist from misrepresenting the extent to which any antifreeze, coolant, or deicer product or its package is capable of being recycled or the extent to which recycling collection programs are available.

Part VI of the proposed order provides that, for up to 100 days after the service of the order, respondents may continue to ship products from existing stock in containers with nonconforming labeling.

The proposed order also requires the respondents to maintain materials relied upon to substantiate the claims covered by the order, to distribute copies of the order to certain company officials, to notify the Commission of any changes in corporate structure that might affect compliance with the order, and to file one or more reports detailing compliance with the order. The order also contains a provision stating that it will terminate after twenty (20) years absent the filing of a complaint against respondents alleging a violation of the order.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

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GENERAL ACCOUNTING OFFICE

Federal Accounting Standards Advisory Board

AGENCY: General Accounting Office.

ACTION: Cancellation of December 14 meeting.

SUMMARY: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. No. 92-463), as amended, notice is hereby given that the previously announced December 14 meeting of the Federal Accounting Standards Advisory Board has been canceled. Agenda issues planned for the December meeting will be discussed at the January 25 meeting, which will be duly announced in a later edition of the Federal Register.

FOR FURTHER INFORMATION CONTACT:

Ronald S. Young, Executive Staff Director, 750 First St., N.E., Room 1001, Washington, D.C. 20002, or call (202) 512-7350.

Authority: Federal Advisory Committee Act, Pub. L. No. 92-463, Section 10(a)(2), 86 Stat. 770, 774 (1972) (current version at 5 U.S.C. app. section 10(a)(2) (1988)); 41 CFR 101-6.1015 (1990).

Dated: December 7, 1995.

Ronald S. Young,

Executive Director.

[FR Doc. 95-30245 Filed 12-11-95; 8:45 am]

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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.