30341–4146, Telephone: (770) 488–2745, e-mail address: *mqg4@cdc.gov.*

For business management and budget assistance in the territories, contact: Charlotte Flitcraft, Grants Management Officer, Procurement and Grants Office, Centers for Disease Control and Prevention, 2020 Brandywine Rd., Atlanta, GA 30319, Telephone: (770) 488–2632, e-mail address: *caf5@cdc.gov.*

For program technical assistance, contact: Kathie Sunnarborg, MPH, CHES, Public Health Advisor, Air Pollution and Respiratory Health Branch, National Center for Environmental Health, Centers for Disease Control and Prevention, 1600 Clifton Rd., NE, Mailstop E–17, Atlanta, GA 30333, Telephone number: (404) 498–1451, e-mail address: *ksunnarborg@cdc.gov.*

Dated: May 21, 2003.

**Sandra R. Manning,**

*Director, Procurement and Grants Office, Centers for Disease Control and Prevention.*

[FR Doc. 03–13222 Filed 5–27–03; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 02P–0479]**

### Determination That Periactin Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined that Periactin (cyproheptadine hydrochloride (HCl)) 4-milligram (mg) tablets were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for cyproheptadine HCl 4-mg tablets.

**FOR FURTHER INFORMATION CONTACT:** Mary Catchings, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

**SUPPLEMENTARY INFORMATION:** In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products with Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162). Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

Periactin 4-mg tablets are the subject of NDA 12–649. On October 17, 1961, Merck & Co., Inc., received approval to market Periactin 4-mg tablets.

On November 5, 2002, CorePharma LLC submitted a citizen petition (Docket No. 02P–0479/CP1) under 21 CFR 10.30 requesting that the agency assign reference listed drug status to a currently marketed cyproheptadine hydrochloride 4-mg tablet drug product. At that time, FDA exercised its discretion under § 314.161(a) to determine if Periactin 4-mg tablets were withdrawn for reasons of safety or effectiveness.

After reviewing agency records, FDA has determined that Periactin 4-mg tablets were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list Periactin 4-mg tablets in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to Periactin 4-mg tablets may be approved by the agency.

Dated: May 19, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 03–13193 Filed 5–27–03; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### FDA/Industry Exchange Workshop on FDA Clinical Trials Statutory and Regulatory Requirements; Public Workshop

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

**ACTION:** Notice of public workshop.

**SUMMARY:** The Food and Drug Administration (FDA) Philadelphia District, in cooperation with the Society of Clinical Research Associates, (SoCRA) is announcing a workshop on FDA clinical trial statutory and regulatory requirements. Topics for discussion include: Financial incentives and funding, pre-IND (investigational new drug application) meetings and FDA meeting process, medical device aspects of clinical research, informed consent requirements, adverse event reporting, how FDA conducts bioresearch inspections, ethics in clinical research, FDA and confidence in the conduct of clinical research, and how FDA addresses fraud in clinical research. This 2-day workshop for the clinical research community targets sponsors, monitors, clinical investigators, institutional review boards and those who interact with them for the purpose of conducting FDA regulated clinical research. The workshop will include both industry and FDA perspectives on proper conduct of clinical trials regulated by FDA.

*Date and Time*: The public workshop is scheduled for Wednesday, June 25, 2003, from 8:30 a.m. to 4:45 p.m. and Thursday, June 26, 2003, from 8:45 a.m. to 4:45 p.m.

*Location*: The public workshop will be held at the Pittsburgh Marriott Center City Hotel, 112 Washington Pl., Pittsburgh, PA 15219.

*Contact*: Daniel R. Tammariello, FDA, 7 Parkway Center, Suite 250, Pittsburgh, PA 15220, 412–644–3394, ext. 16, FAX: 412–644–4496, e-mail: *dtammari@ora.fda.gov* or Marie Falcone, Industry and Small Business Representative, FDA, Room 900 U.S. Customhouse, 200 Chestnut St.,