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Determination That Periactin Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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(FDA) has determined that Periactin (cyproheptadine hydrochloride (HCl)) 4-milligram (mg) tablets were not withdrawn from sale for reasons of safety or effectiveness.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.,

Philadelphia, PA 19106, 215–597–2120, ext. 4003, FAX: 215–597–5798, e-mail: *mfalcone@ora.fda.gov.*

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) and $460 (member) or $535 (non-member) registration fee made payable to SoCRA, P.O. Box 101, Furlong, PA 18925. To register via the Internet go to *http://www.socra.org/FDA_Conference.htm.* FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.

Registrar will also accept payment by major credit cards. For more information on the meeting, or for questions on registration, contact 800 -SoCRA92 (800–762–7292), or 215–345–7369 or via e-mail to *socramail@aol.com.* Attendees are responsible for their own accommodations. To make reservations at the Pittsburgh Marriott Center City Hotel at the reduced conference rate, contact the Pittsburgh Marriott Center City Hotel at 412–471–4000 or 888–456–6600 or by fax at hotel FAX: 412–281–4797 before June 3, 2003.

The registration fee will be used to offset the expenses of hosting the conference, including meals, refreshments, meeting rooms, and materials. Space is limited, therefore interested parties are encouraged to register early. Limited onsite registration may be available. Please arrive early to ensure prompt registration.

If you need special accommodations due to a disability, please contact Marie Falcone at least 7 days in advance of the workshop.

SUPPLEMENTARY INFORMATION: The ''FDA Clinical Trials Statutory and Regulatory Requirements'' workshop helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health by educating researchers on proper conduct of clinical trials. FDA has made education of the research community a high priority to assure the quality of clinical data and protect research subjects.

The workshop helps to implement the objectives of section 406 of the FDA Modernization Act (21 U.S.C. 393) and the FDA Plan for Statutory Compliance, which includes working more closely with stakeholders and ensuring access to needed scientific and technical expertise. The workshop also furthers the goals of the Small Business Regulatory Enforcement Fairness Act (Public Law 104–121) by providing outreach activities by Government agencies directed to small businesses.

Dated: May 20, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–13192 Filed 5–27–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Web-based Semi Annual Report (SAR) (OMB No. 0915–0262)—Revision

The Health Resources and Services Administration (HRSA), Bureau of Primary Health Care (BPHC) plans to collect the annual reporting requirements for the primary care grantees funded by BPHC using the web-based Semi Annual Report (SAR). The SAR includes reporting requirements for grantees of the following primary care programs: State Primary Care Associations and State Primary Care Offices. Authorizing legislation is found in Section 330(m) of the Public Health Service Act, as amended.

BPHC collects data on its programs to ensure compliance with legislative mandates and to report to Congress and policy makers on program accomplishments. To meet these objectives, BPHC requires a core set of information collected semi-annually that is appropriate for monitoring and evaluating performance and reporting on annual trends. The SAR has been a valuable instrument for collecting this information from grantees. The SAR provides data on services, characteristics of populations, leveraged funds, and services that fall within the scope of the grant.

The estimated burden is as follows:

Form	Number of respondents	Responses per respondent	Hours per response	Total burden hours
SAR	103	1	18	1854

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 14–45, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: May 20, 2003.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 03–13224 Filed 5–27–03; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Availability of Funds

AGENCY: Health Resources and Services Administration (HRSA), HHS.