

determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

If a listed drug is withdrawn from sale and there are approved ANDAs that refer to that drug, under § 314.161(a)(2) (21 CFR 314.161(a)(2)), the agency must determine whether the listed drug was withdrawn from sale for reasons of safety or effectiveness. Section 314.161(d) provides that if FDA determines that the listed drug was removed from sale for safety or effectiveness reasons, the agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

The holders of the applications listed in the table in this document have informed FDA that the drug products have been withdrawn from sale. The drug products in the table are subjects of approved NDAs to which one or more approved ANDAs refer.

| NDA No. | Drug | Applicant |
|---------|--|--|
| 10-775 | Trilafon (perphenazine) tablets, 2, 4, 8, and 16 milligrams (mg) | Schering Corp., 2000 Galloping Hill Rd., Kenilworth, NJ 07033 |
| 12-071 | Decadron (dexamethasone sodium phosphate) injection, 4 mg/milliliter (mL) and 24 mg/mL | Merck & Co., P.O. Box 4, West Point, GA 19486-0004 |
| 14-694 | Hexadrol (dexamethasone sodium phosphate) injection, 4 mg/mL and 10 mg/mL | Organon, Inc., 375 Mt. Pleasant Ave., West Orange, NJ 07052 |
| 19-304 | Tricor (fenofibrate) capsules, 67, 134, and 200 mg | Abbott Laboratories, 200 Abbott Park Rd., Abbott Park, IL 60064-3537 |

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Approved ANDAs that refer to the NDAs listed in this document are unaffected by the withdrawal of these products subject to those NDAs, and accordingly, the agency will continue to list the drug products listed in this document in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Dated: September 17, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA).

The meeting will be open to the public.

Name of Committee: Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 9, 2003, from 8 a.m. to 4:30 p.m.

Location: Holiday Inn, Kennedy Ballroom, 8777 Georgia Ave., Silver Spring, MD.

Contact Person: Thomas H. Perez, Center for Drug Evaluation and Research, (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery: 5630 Fishers Lane, Rm. 1093) Rockville, MD 20857, by phone at 301-827-6758, or by e-mail at PerezT@cder.fda.gov or the FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12542. Please call the Information Line for up-to-date information on this meeting.

Agenda: The subcommittee will: (1) Consider off-patent oncology drugs for which pediatric studies are needed and discuss the availability of information concerning the safe and effective use of the drugs in the pediatric population, whether additional information is needed, and whether new pediatric studies concerning the drugs may produce health benefits in the pediatric population, as mandated by the Best Pharmaceuticals for Children Act (BPCA), and (2) discuss age-appropriate formulation changes to facilitate dosing of products used in the pediatric oncology setting.

Procedure: Interested persons may present data, information, or views,

orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by October 2, 2003. Oral presentations from the public will be scheduled between approximately 10 a.m. and 10:30 a.m. and 1 p.m. and 1:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 2, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets. FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please notify Thomas Perez at least 7 days in advance of the meeting.

FDA regrets that it was unable to publish this notice 15 days prior to the October 9, 2003, Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 26, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03-24920 Filed 9-26-03; 4:13 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of 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 a meeting of the Director's Council of Public Representatives.