withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of NILSTAT (nystatin powder (oral, 100%)) from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events and have found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list NILSTAT (nystatin powder (oral, 100%)) 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 NILSTAT (nystatin powder (oral, 100%)) may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: February 24, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011–4595 Filed 3–1–11; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2010–N–0318]**

### Determination That MEGACE (Megestrol Acetate) Tablets and Nine Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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The Food and Drug Administration (FDA) has determined that the 10 drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

**FOR FURTHER INFORMATION CONTACT:** Olivia Pritzlaff, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6308, Silver Spring, MD 20993–0002, 301–796–3601.

**SUPPLEMENTARY INFORMATION:** In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants 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. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (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 (the FD&C 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, a drug is 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) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved; (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved; and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for reasons of safety or effectiveness, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table in this document are no longer being marketed. (As requested by the applicants, FDA withdrew approval of NDA 18–101 for SYMMETREL (amantadine hydrochloride (HCl)) Tablets and ANDA 84–935 for DEXEDRINE (dextroamphetamine sulfate) Tablets in the **Federal Register** of July 21, 2010 (75 FR 42455).)

| Application No. | Drug | Applicant |
|---|---|---|
| NDA 16–979 | MEGACE (megestrol acetate) Tablets, 20 milligrams (mg) and 40 mg. | Bristol Myers Squibb, P.O. Box 4000, Princeton, NJ 08543–4000. |
| NDA 17–911 | CLINORIL (sulindac) Tablet, 150 mg | Merck Research Laboratories, Sumneytown Pike, West Point, PA 19486. |
| NDA 18–101 | SYMMETREL (amantadine HCl) Tablet, 100 mg | Endo Pharmaceuticals, Inc., 100 Endo Blvd., Chadds Ford, PA 19317. |
| NDA 18–482 | PROCARDIA (nifedipine) Capsule, 20 mg | Pfizer Inc., 235 East 42nd St., New York, NY 10017–5755. |
| NDA 18–768 | VEPESID (etoposide) Injection, 20 mg/milliliter (mL) | Bristol Myers Squibb. |
| NDA 20–262 | TAXOL (paclitaxel) Injection, 6 mg/mL | Do. |
| NDA 20–450 | CEREBYX (fosphenytoin sodium) Injection, Equivalent to (EQ) 50 mg phenytoin sodium/mL. | Parke Davis, 2800 Plymouth Rd., Ann Arbor, MI 48106–1047. |
| NDA 50–527 | DURICEF (cefadroxil/cefadroxil hemihydrate) Oral Suspension, EQ 250 mg base/5mL and EQ 500 mg base/5 mL. | Warner Chilcott, Inc., 100 Enterprise Dr., Suite 280, Rockaway, NJ 07866. |
| ANDA 84–051 | DEXTROSTAT (dextroamphetamine sulfate) Tablets, 5 mg and 10 mg. | Shire Development, Inc., 725 Chesterbrook Blvd., Wayne, PA 19087. |

| Application No. | Drug | Applicant |
|---|---|---|
| ANDA 84–935 ..... | DEXEDRINE (dextroamphetamine sulfate) Tablet, 5 mg .... | GlaxoSmithKline, 5 Moore Dr., P.O. Box 13398, Research Triangle Park, NC 27709–3398. |

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. 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.

Approved ANDAs that refer to the NDAs listed in this document are unaffected by the discontinued marketing of the products subject to those NDAs. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines the labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: February 24, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011–4594 Filed 3–1–11; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2011–N–0002]**

### 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:* 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 April 12, 2011, from 8 a.m. to 5 p.m.

*Location:* FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading "Resources for You," click on "White Oak Conference Center Parking and Transportation Information for FDA Advisory Committee Meetings." Please note that visitors to the White Oak Campus must enter through Building 1.

*Contact Person:* Caleb Briggs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, *e-mail: caleb.briggs@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

*Agenda:* On April 12, 2011, during the morning session, the committee will discuss supplemental new drug application (sNDA) 022334/S–009, trade name AFINITOR (everolimus) tablets, application submitted by Novartis Pharmaceuticals Corp. The proposed indication (use) for this product is for the treatment of patients with advanced neuroendocrine tumors (NET) of gastrointestinal, lung, or pancreatic origin.

During the afternoon session, the committee will discuss sNDA 021938/S–013, trade name SUTENT (sunitinib malate) capsules, application submitted by C.P. Pharmaceuticals International C.V., represented by Pfizer, Inc. (authorized U.S. agent). The proposed indication (use) for this product is for the treatment of unresectable pancreatic neuroendocrine tumors (PNET).

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee link.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before March 29, 2011. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 11 a.m. and 3:30 p.m. to 4 p.m. Those individuals interested in making formal oral presentations should notify the contact person 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 on or before March 21, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by March 22, 2011.

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 contact Caleb Briggs at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/*