anticipate manufacturing dissolvable tobacco products will take approximately 1 hour to draft and send a letter to FDA indicating that they do not have documents to submit. These estimates were derived based upon FDA experience and feedback provided by public and stakeholder comments.

The capital costs associated with this collection pertain to the postage for mailing documents in electronic or paper formats. Estimating these costs is problematic because the costs will vary depending on the size of the document production (*e.g.* one binder of documents vs. numerous boxes of paper) and the media type (*e.g.,* compact disk (CD) or digital video disk) chosen to submit documents. Currently, we cannot identify how many documents will be submitted per response.

Some sample postage costs are shown for different types of packages:

- 10 CDs in a flat envelope weighing 30 ounces: approximately $8.00 using first class business mail
- 5-pound parcel containing paper documents: approximately $12 using business parcel post mail and delivering to the furthest delivery zone
- 10-pound parcel containing paper documents: approximately $17 using business parcel mail and delivering to the furthest delivery zone
- 50-pound parcel containing paper documents: approximately $52 using business parcel post mail and delivering to the furthest delivery zone.

FDA estimates the capital costs associated with this document submission to be $924. The capital costs determined by this estimate are based upon 3 submissions for large manufacturers, 7 submissions for small to medium manufacturers, and 110 submissions of 1 letter apiece for those who do not either manufacture dissolvable tobacco products or have documents pertaining to the manufacture of dissolvable tobacco products.

For the three large manufacturers, it is estimated that each manufacturer will submit their documents electronically on the equivalent of one 500-gigabyte external hard drive of data. This is estimated to cost approximately $125 per drive, and $20 to ship the drive, for a total of $435 (3 manufacturers × [$125 + $20]).

For the 7 small to medium sized manufacturers, it is estimated that 5 manufacturers (about 71 percent) will submit their documents electronically on the equivalent of 10 CD–ROMs. This is estimated to cost $20 for the 10 CD–ROM spindle, and $8 to ship each group of 10 CDs per envelope for a total of $140 (5 manufacturers × [$20 + $8]). The remaining two manufacturers will submit their documents via paper, which is estimated to cost $184 (2 manufacturers × [$40 cost of one box of paper + $52 to ship the box of paper]). The total capital cost for small to medium manufacturers, therefore, is estimated to be $324 ($140 + $184).

For the remaining 110 manufacturers who must submit a letter to FDA indicating that they do not have any documents, it is estimated that each manufacturer will use $1 of paper products and pay postage approximating a rounded figure of $0.50 for a total of $165 (110 manufacturers × [$1.00 + $0.50]). Therefore, FDA estimates the total capital costs associated with this document submission to be $924.

Dated: February 24, 2011.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2011–4613 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–P–0201]

Determination That NILSTAT (Nystatin Powder (Oral, 100%)) 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 NILSTAT (nystatin powder (oral, 100%)) was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for nystatin powder (oral, 100%) if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Jennifer L. Stevens, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6316, Silver Spring, MD 20993–0002, 301–796–3602.

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 (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 removed 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.

NILSTAT (nystatin powder (oral, 100%)) is the subject of NDA 050576, held by Dava Pharmaceuticals, Inc., and was initially approved on December 22, 1983. NILSTAT is indicated for the treatment of intestinal and oral cavity infections caused by *Candida (Monilia) albicans*. NILSTAT (nystatin powder (oral, 100%)) is currently listed in the "Discontinued Drug Product List" section of the Orange Book.

Paddock Laboratories, Inc., submitted a citizen petition dated April 8, 2010 (Docket No. FDA–2010–P–0201), under 21 CFR 10.30, requesting that the Agency determine whether NILSTAT (nystatin powder (oral, 100%)) was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records, FDA has determined under § 314.161 that NILSTAT (nystatin powder (oral, 100%)) was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that NILSTAT (nystatin powder (oral, 100%)) was

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.