TABLE 1—Continued

Application No.	Drug	Applicant	Initial approval date
NDA 50–725	AUGMENTIN '200' (amoxicillin; clavulanate potassium) Powder for Oral Suspension, 200 mg/5 milliliters (mL); EQ 28.5 mg base/5 mL.	Do	May 31, 1996.
Do	AUGMENTIN '400' (amoxicillin; clavulanate potassium) Powder for Oral Suspension, 400 mg/5 mL; EQ 57 mg base/5 mL.	Do	Do.
NDA 50–726	AUGMENTIN '200' (amoxicillin; clavulanate potassium) Chewable Tablet, 200 mg; EQ 28.5 mg base.	Do	Do.
Do	AUGMENTIN '400' (amoxicillin; clavulanate potassium) Chewable Tablet, 400 mg; EQ 57 mg base.	Do	Do.
NDA 50–755	AUGMENTIN ES–600 (amoxicillin; clavulanate potassium) Powder for Oral Suspension, 600 mg/5 mL; EQ 42.9 mg base/5 mL.	SmithKline Beecham d/b/a GlaxoSmithKline, One Franklin Plaza, Philadelphia, PA 19101.	June 22, 2001.

In a letter dated November 10, 2009, GlaxoSmithKline notified FDA that the AUGMENTIN (amoxicillin; clavulanate potassium) products listed in this document, among other drug products, were being discontinued, and FDA moved the drug products to the "Discontinued Drug Product List" section of the Orange Book. Approved ANDAs for the AUGMENTIN (amoxicillin; clavulanate potassium) products listed in this document are listed in the Orange Book, and following the discontinuation of the AUGMENTIN (amoxicillin; clavulanate potassium) products, ANDAs for certain of these products were designated as the reference listed drugs to which new ANDAs should refer.

EAS Consulting Group, LLC, submitted two citizen petitions dated March 23, 2010 (FDA–2010–P–0172), and March 26, 2010 (FDA–2010–P–0177), under 21 CFR 10.30, requesting that the Agency determine whether the following products were withdrawn from sale for reasons of safety or effectiveness:

- AUGMENTIN '200' (amoxicillin; clavulanate potassium) Powder for Oral Suspension, 200 mg/5 mL; EQ 28.5 mg base/5 mL;
- AUGMENTIN '400' (amoxicillin; clavulanate potassium) Powder for Oral Suspension, 400 mg/5 mL; EQ 57 mg base/5 mL; and
- AUGMENTIN ES–600 (amoxicillin; clavulanate potassium) Powder for Oral Suspension, 600 mg/5 mL; EQ 42.9 mg base/5 mL.

Although the citizen petitions did not address the other AUGMENTIN (amoxicillin; clavulanate potassium) products listed in this document, those products have also been discontinued. On our own initiative, we have also determined whether those products were withdrawn for safety or effectiveness reasons.

After considering the citizen petitions and reviewing Agency records, FDA has determined under § 314.161 that the AUGMENTIN (amoxicillin; clavulanate potassium) products listed in this document were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that the AUGMENTIN (amoxicillin; clavulanate potassium) products listed in this document were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of the AUGMENTIN (amoxicillin; clavulanate potassium) products listed in this document. We have also independently evaluated relevant literature and data for possible postmarketing adverse events and have found no information that would indicate that these products were withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list the AUGMENTIN (amoxicillin; clavulanate potassium) products listed in this document 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. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to the AUGMENTIN (amoxicillin; clavulanate potassium) products listed in this document. Additional ANDAs that refer to these products may also 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 these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: December 1, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–30622 Filed 12–6–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–P–0275]

Determination That GLEEVEC (Imatinib Mesylate) Capsules, 50 Milligrams and 100 Milligrams, 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 GLEEVEC (imatinib mesylate) Capsules, 50 milligrams (mg) and 100 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for imatinib mesylate capsules, 50 mg and 100 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Rochelle Chodock Fink, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6236, Silver Spring, MD 20993–0002, 301–796–0838.

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 known generally as the "Orange Book." Under FDA regulations, drugs are 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.

GLEEVEC (imatinib mesylate) Capsules, 50 mg and 100 mg, are the subject of NDA 21–335, held by Novartis Pharmaceutical Corp., and initially approved on May 10, 2001. GLEEVEC is a protein-tyrosine kinase inhibitor used in the treatment of a variety of malignancies, including Ph+ chronic myeloid leukemia and acute lymphoblastic leukemia, myelodysplastic/myeloproliferative diseases, aggressive systemic mastocytosis, hypereosinophilic syndrome, chronic eosinophilic leukemia, dermatofibrosarcoma protuberans, and gastrointestinal stromal tumors. FDA has moved GLEEVEC (imatinib mesylate) Capsules, 50 mg and 100 mg, to the "Discontinued Drug Product List" section of the Orange Book.

Hyman, Phelps & McNamara, PC, submitted a citizen petition dated June 3, 2010 (Docket No. FDA–2010–P–0275), under 21 CFR 10.30, requesting that the Agency determine whether GLEEVEC (imatinib mesylate) Capsules, 50 mg and 100 mg, were 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 GLEEVEC (imatinib mesylate) Capsules, 50 mg and 100 mg were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that GLEEVEC (imatinib mesylate) Capsules, 50 mg and 100 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of GLEEVEC (imatinib mesylate) capsules, 50 mg and 100 mg, 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 these products were withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list GLEEVEC (imatinib mesylate) Capsules, 50 mg and 100 mg, 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 GLEEVEC (imatinib mesylate) Capsules, 50 mg and 100 mg, 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 these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: December 1, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–30570 Filed 12–6–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

Third Annual Sentinel Initiative Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing the following public workshop: Third Annual Sentinel Initiative Public Workshop. Hosted by the Engelberg Center for Health Care Reform at The Brookings Institution, this 1-day public workshop will bring together the stakeholder community for a productive discussion on a variety of topics in active medical product surveillance, including an update on Mini-Sentinel and related activities, near-term plans for FDA's Sentinel Initiative, and opportunities for coordination with other U.S. Department of Health and Human Services efforts that use distributed systems of automated health care data.

Date and Time: The public workshop will be held on January 12, 2011, from 8:30 a.m. to 4:30 p.m.

Location: The public workshop will be held at the Renaissance Dupont Hotel, 1143 New Hampshire Ave. NW., Washington, DC 20037.

Contact: Kayla Garvin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6331, Silver Spring, MD 20993, 301–796–7578, e-mail: *sentinelinitiative@fda.hhs.gov.*

Registration: To attend the public workshop, please register at *http://guest.cvent.com/d/hdq5r4/1Q.* When registering, provide the following information: Your name, title, company or organization (if applicable), address, phone number, and e-mail address. There is no fee to register for the public workshop, but because seating is limited, registration will be on a first-come, first-served basis. A 1-hour lunch break is scheduled; however, food will not be provided. There are multiple restaurants within walking distance of the hotel where attendees can get food. If you need special accommodations due to a disability, please contact The Brookings Institution event coordinator at 202–797–4391 or e-mail: *sentinelevent@brookings.edu* at least 7 days in advance.

Meeting Materials: Please be advised that as soon as workshop materials are available, they will be accessible at The Brookings Institution events Web site at *http://www.brookings.edu//health/events.*

Dated: December 1, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–30562 Filed 12–6–10; 8:45 am]

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