FOR FURTHER INFORMATION CONTACT: Sean M. Boyd, Center for Devices and Radiological Health, Office of Communication, Education, and Radiological Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4640, Silver Spring, MD 20993–0002, 301–796–5895.

SUPPLEMENTARY INFORMATION: In a notice containing a cumulative list of guidances available from the Agency that published in the **Federal Register** of August 9, 2010 (75 FR 48180 at 48233), FDA included the Compliance Policy Guides Manual, which includes CPG Sec. 393.200. FDA is withdrawing CPG Sec. 393.200 because it is obsolete.

Dated: November 23, 2010.

Dara Corrigan,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 2010–30679 Filed 12–6–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2010–P–0172 and FDA–2010–P–0177]

Determination That AUGMENTIN '125' (Amoxicillin; Clavulanate Potassium) Chewable Tablet and Six Other AUGMENTIN (Amoxicillin; Clavulanate Potassium) Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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has determined that the AUGMENTIN (amoxicillin; clavulanate potassium) drug products listed in this notice were not withdrawn from sale for reasons of safety or effectiveness.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: Molly Flannery, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6237, Silver Spring, MD 20993–0002, 301–796–3543.

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, 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. Under § 314.161(a)(2), FDA must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved. 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.

The drug products listed in table 1 of this document are no longer being marketed. Six of the products listed (AUGMENTIN '125' Chewable Tablet, AUGMENTIN '250' Chewable Tablet, AUGMENTIN '200' Powder for Suspension, AUGMENTIN '400' Powder for Suspension, AUGMENTIN '200' Chewable Tablet, and AUGMENTIN '400' Chewable Tablet) are indicated for the treatment of infections caused by susceptible strains of the designated organisms in the following conditions: Lower respiratory tract infections, caused by β-lactamase-producing strains of *Haemophilus influenzae* and *Moraxella catarrhalis;* otitis media, caused by β-lactamase-producing strains of *H. influenzae* and *M. catarrhalis;* sinusitis, caused by β-lactamase-producing strains of *H. influenzae* and *M. catarrhalis;* skin and skin structure infections, caused by β-lactamase-producing strains of *Staphylococcus aureus, Escherichia coli,* and *Klebsiella* spp.; and urinary tract infections, caused by β-lactamase-producing strains of *E. coli, Klebsiella* spp., and *Enterobacter* spp. AUGMENTIN ES–600 Powder for Suspension is indicated for the treatment of pediatric patients with recurrent or persistent acute otitis media due to *Streptococcus pneumoniae* (penicillin MICs ≤ 2 micrograms (mcg)/mL), *H. influenzae* (including β-lactamase-producing strains), or *M. catarrhalis* (including β-lactamase-producing strains) characterized by the following risk factors: antibiotic exposure for acute otitis media within the preceding 3 months, and either age ≤ 2 years or daycare attendance.

TABLE 1

Application No.	Drug	Applicant	Initial approval date
NDA 50–597	AUGMENTIN '125' (amoxicillin; clavulanate potassium) Chewable Tablet, 125 milligrams (mg); Equivalent to (EQ) 31.25 mg base.	GlaxoSmithKline, One Franklin Plaza, Philadelphia, PA 19101.	July 22, 1985.
Do	AUGMENTIN '250' (amoxicillin; clavulanate potassium) Chewable Tablet, 250 mg; EQ 62.5 mg base.	Do	Do.

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