VIII. Office of the Commissioner

<table>
<thead>
<tr>
<th>Guidance title/TOPIC</th>
<th>OC Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classification of products as biological products, devices, and drugs</td>
<td>John Weiner, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave, Silver Spring, MD 20993 301–796–8941.</td>
</tr>
<tr>
<td>Interpretation of the term “chemical action” in definition of device under section 201(h) of the Federal Food, Drug, and Cosmetic Act.</td>
<td>Do.</td>
</tr>
<tr>
<td>Types of submissions for postapproval changes to combination products</td>
<td>Do.</td>
</tr>
<tr>
<td>Information Sheet Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors—FDA Inspections of Clinical Investigators Describes FDA’s inspectional process when the agency inspects the site of an investigator who is conducting a clinical study regulated by FDA.</td>
<td>Bridget Foltz, Office of Good Clinical Practices, Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993, 301–796–8348.</td>
</tr>
<tr>
<td>Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors—Exception From Informed Consent Requirements for Emergency Research This final guidance is intended to assist sponsors, clinical investigators, and IRBs in the development, conduct, and oversight of research involving FDA-regulated products (e.g., drugs, biological products, devices) in emergency settings when an exception from the informed consent requirements is requested under 21 CFR 50.24. In particular, the guidance clarifies FDA’s expectations related to planning and conducting community consultation and public disclosure activities, and the establishment of informed consent procedures to be used when feasible.</td>
<td>Sara Goldkind, Office of Good Clinical Practices, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–8348.</td>
</tr>
</tbody>
</table>

Dated: December 1, 2010.

Leslie Kux,
Acting Assistant Commissioner for Policy.

[FR Doc. 2010–30623 Filed 12–6–10; 8:45 am]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0551]

Compliance Policy Guide Sec. 393.200 Laser(s) as Medical Devices for Facelift, Wrinkle Removal, Acupuncture, Auricular Stimulation, etc.; Withdrawal of Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of Compliance Policy Guide Sec. 393.200 Laser(s) as Medical Devices for Facelift, Wrinkle Removal, Acupuncture, Auricular Stimulation, etc. (CPG Sec. 393.200). CPG Sec. 393.200 is included in FDA’s Compliance Policy Guides Manual, which was listed in the Annual Comprehensive List of Guidance Documents that published on August 9, 2010.

DATES: The withdrawal is effective December 7, 2010.
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 drugs. FDA will allow ANDAs to continue to be approved.

AUGMENTIN ‘125’ (amoxicillin; clavulanate potassium) Chewable Tablet, 125 milligrams (mg): Equivalent to (EQ) 31.25 mg base.

AUGMENTIN ‘250’ (amoxicillin; clavulanate potassium) Chewable Tablet, 250 mg: EQ 62.5 mg base.

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.

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

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.

Federal Register

FOR FURTHER INFORMATION CONTACT:
Dara Corrigan, Associate Commissioner for Regulatory Affairs. [FR Doc. 2010–30679 Filed 12–6–10; 8:45 am]

BILLING CODE 4160–01–P

Do ........................................................................ Do.

Do ........................................................................ Do.

Drug applications (ANDAs) that refer to a listed drug may be approved if FDA determines that the listed drug is bioequivalent to the drug that was previously approved. 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)(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 beta-lactamase-producing strains of Haemophilus influenzae and Moraxella catarrhalis; otitis media, caused by beta-lactamase-producing strains of H. influenzae and M. catarrhalis; sinusitis, caused by beta-lactamase-producing strains of H. influenzae and M. catarrhalis; skin and skin structure infections, caused by beta-lactamase-producing strains of Staphylococcus aureus, Escherichia coli, and Klebsiella spp.; and urinary tract infections, caused by beta-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 beta-lactamase-producing strains), or M. catarrhalis (including beta-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

<table>
<thead>
<tr>
<th>Application No.</th>
<th>Drug</th>
<th>Applicant</th>
<th>Initial approval date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do</td>
<td>AUGMENTIN ‘250’ (amoxicillin; clavulanate potassium) Chewable Tablet, 250 mg: EQ 62.5 mg base.</td>
<td>Do .......................................................... Do.</td>
<td></td>
</tr>
</tbody>
</table>