Title of Guidance	Contact
Draft Guidance for Industry—Active Controls in Studies to Demonstrate the Effectiveness of a New Drug for Use in Companion Animals.	Lisa Troutman, Center for Veterinary Medicine (HFV–116), Food and Drug Administration, 7500 Standish Pl., MPN–2, rm. N319, Rockville, MD 20855, 240–276–8322, *lisa.troutman@fda.hhs.gov.*
Residual Solvents in Animal Drug Products; Questions and Answers	Sudesh Kamath, Center for Veterinary Medicine (HFV–145), Food and Drug Administration, 7500 Standish Pl., MPN–2, rm. E365, Rockville, MD 20855, 240–276–8260, *sudesh.kamath@fda.hhs.gov.*
Draft Guidance for Industry—Updating Labeling of Certain Antimicrobial New Animal Drug Products for Use in the Feed or Water of Food-Producing Animals.	William Flynn, Center for Veterinary Medicine (HFV–1), Food and Drug Administration, 7519 Standish Pl., MPN–4, rm. 173, Rockville, MD 20855, 240–276–9084, *William.flynn@fda.hhs.gov.*
Final Guidance for Industry—Bracketing and Matrixing Designs for Stability Testing of New Veterinary Drug Substances and Medicinal Products, VICH GL–45.	Dennis Bensley, Center for Veterinary Medicine (HFV–140), Food and Drug Administration, 7500 Standish Pl., MPN–2, rm. E334, Rockville, MD 20855, 240–276–8268, *dennis.bensley@fda.hhs.gov.*
Revised Draft Guidance for Industry—Impurities: Residual Solvents In New Veterinary Medicinal Products, Active Substances and Excipients, VICH GL18(R).	Mai, Huynh, Center for Veterinary Medicine, (HFV–142), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8273, *Mai.huynh@fda.hhs.gov.*
Draft Guidance for Industry—Evaluating the Effectiveness of Anticoccidial Drugs in Food-Producing Animals.	Emily R. Smith, (HFV–135), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8344, e-mail: *emily.smith2@fda.hhs.gov.*
Draft Guidance for Industry—Protocol Submissions for the Division of Therapeutic Drugs for Non-Food Animals the Division of Production Drugs, and the Division of Therapeutic Drugs for Food Animals.	Angela Clarke, Center for Veterinary Medicine (HFV–105), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8318; e-mail: *angela.clarke@fda.hhs.gov.*

VIII. Office of the Commissioner

Guidance title/TOPIC	OC Contact
• Classification of products as biological products, devices, and drugs	John Weiner, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave, Silver Spring, MD 20993 301–796–8941.
• Interpretation of the term "chemical action' in definition of device under section 201(h) of the Federal Food, Drug, and Cosmetic Act.	Do.
• Types of submissions for postapproval changes to combination products	Do.
• 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.	Bridget Foltz, Office of Good Clinical Practices, Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993, 301–796–8348.
• Draft Information Sheet Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors—A Guide to Informed Consent Describes in detail basic and additional elements of informed consent and includes topics such as review of patient records, children as subjects, and subject participation in more than one study.	Sara Goldkind (301–796–8342), Marsha Melvin (301–796–8345), Office of Good Clinical Practices, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993.
• 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.	Sara Goldkind, Office of Good Clinical Practices, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–8348.

Dated: December 1, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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

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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.

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]

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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.