4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0779]

Retrospective Review of Draft Guidance Documents Issued Before 2010; Withdrawal of Guidances

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an initiative in the Center for Drug Evaluation and Research (CDER) involving the review of draft guidance documents issued before 2010 to determine their status, and to decide whether those guidances should be withdrawn, revised, or finalized with only minor changes. Guidances that are no longer up to date, and for which more current information is available, will be withdrawn. Guidances that reflect CDER's current thinking, CDER will decide whether to revise or finalize. This notice describes CDER's initiative, announces the first group of guidances to be withdrawn, describes in general terms draft guidances under consideration for revision or finalization, and explains how CDER is making this process as transparent as possible.

DATES: General comments on Agency guidance documents are welcome at any time.

ADDRESSES: Submit electronic comments on Agency guidance documents to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the SUPPLEMENTARY INFORMATION section for electronic access to Agency guidance documents.

FOR FURTHER INFORMATION CONTACT: Kimberly K. Thomas, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6220, Silver Spring, MD 20993-0002, 301-796-2357, kimberly.k.thomas@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In September 2000, FDA issued the final rule "Administrative Practices and Procedures; Good Guidance Practices" (GGP) (65 FR 56468; September 19, 2000). The GGP regulation describes FDA policies and procedures for the development, issuance, and use of guidance documents and makes these Agency policies and procedures clear to the public. The GGP regulation provides for developing and issuing guidances that set forth initial interpretations of statutory or regulatory requirements, explain changes in interpretation of policies that are of other than minor in nature, or discuss complex scientific issues or highly controversial issues. The GGP regulation also requires that such guidances be issued in draft for public comment before they are finalized (Level 1 guidances). In addition, the GGP regulation explains that FDA will periodically review existing guidance documents to determine whether they need to be changed or withdrawn.

A key component of the GGP regulation is ensuring transparency during guidance development and issuance. Since finalization of the GGP regulation in September 2000, CDER has issued an average of approximately 20 draft guidances each year, seeking public input and carefully considering that input before issuing final versions of the guidances. In many cases, guidances were not finalized most often because of higher staff priorities. However, over the

years, because of new information, scientific developments, and emerging technologies, draft guidances were also revised, and reissued or withdrawn.[1]

Recently, CDER launched an initiative to review draft guidance documents published before 2010 to decide which guidances to withdraw, revise, or finalize with only minor changes. CDER is withdrawing draft guidances that are no longer up to date. CDER is also actively reviewing the draft guidances to determine which ones to either revise or finalize. This notice lists the first group of guidances CDER has identified for withdrawal, describes generally what guidances are being reviewed, and describes how CDER will keep the public informed of the guidances that are available with the goal of making the initiative transparent and consistent with the GGP regulation (21 CFR 10.115).

II. Withdrawal of Guidances

CDER has reviewed many draft guidances published before 2010. As a result of this review, CDER identified 23 draft guidances for withdrawal. The guidances are being withdrawn because they are out of date, thus of little use to the pharmaceutical industry. In most cases, FDA has developed other guidances and resources to assist industry with clinical evaluation and requirements for drug approval. The guidances identified for withdrawal relate to these topics:

- Current good manufacturing practice (cGMP) compliance specific to manufacturing, processing, and dose unit sampling and assessment;
- Development of antimicrobial drugs for the treatment of acute bronchitis, bacterial meningitis, bacterial prostatitis, bacterial vaginosis, catheter-related bloodstream

[1] When Level 1 guidances are revised, they are usually issued as draft, version 2s, for public input before being issued in final form. When a guidance needs to be withdrawn, a notice is sometimes published in the Federal Register announcing that the guidance has been withdrawn. If no withdrawal announcement is made, CDER maintains a current list of new/revised/withdrawn guidances on the CDER guidance Web page at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm

infections, febrile neutropenia, gonorrhea, Lyme disease, streptococcal pharyngitis and tonsillitis, uncomplicated urinary tract infections, and vuvlovaginal candidiasis;

- Clinical trials for developing antimicrobial drugs and packaging of inhalation products in semipermeable container systems;
- Approval of abbreviated new drug applications (ANDAs) and 505(b)(2) applications under the Drug Price Competition and Patent Term Restoration Act of 1984 (i.e., the Hatch-Waxman Act);
- Procedures relating to submission of patent information, submission of marketing applications, and forms for registration and disclosure of information;
- Labeling in ANDAs; and
- Qualifying for pediatric exclusivity under the Best Pharmaceuticals for Children Act.

CDER is withdrawing the following guidances:

1. "Manufacturing, Processing, or Holding Active Pharmaceutical Ingredients"--issued April 1998.

2. "Powder Blends and Finished Dosage Units--Stratified In-Process Dosage Unit Sampling and Assessment"--issued November 2003.

3. "Forms for Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution"--issued May 2001.

4. "Disclosing Information Provided to Advisory Committees in Connection With Open Advisory Committee Meetings Related to the Testing or Approval of New Drugs and Convened by CDER, Beginning on January 1, 2000"--issued December 1999.

For information on the four preceding guidances, contact the Office of Compliance in CDER.

5. "Evaluating Clinical Studies of Antimicrobials in the Division of Anti-Infective Drug Products"--issued February 1997.

6. "Empiric Therapy of Febrile Neutropenia--Developing Antimicrobial Drugs for Treatment"--issued July 1998.

7. "Lyme Disease--Developing Antimicrobial Drugs for Treatment"--issued July 1998.

8. "Secondary Bacterial Infections of Acute Bronchitis--Developing Antimicrobial Drugs for Treatment"--issued July 1998.

9. "Streptococcal Pharyngitis and Tonsillitis--Developing Antimicrobial Drugs for Treatment"--issued July 1998.

10. "Uncomplicated Gonorrhea--Developing Antimicrobial Drugs for Treatment"--issued July 1998.

11. "Uncomplicated Urinary Tract Infections--Developing Antimicrobial Drugs for Treatment"--issued July 1998.

12. "Vulvovaginal Candidiasis--Developing Antimicrobial Drugs for Treatment"--issued July 1998.

13. "Bacterial Vaginosis--Developing Antimicrobial Drugs for Treatment"--issued July 1998.

14. "Acute Bacterial Meningitis--Developing Antimicrobial Drugs for Treatment"--issued July 1998.

15. "Acute or Chronic Bacterial Prostatitis--Developing Antimicrobial Drugs for Treatment"--issued July 1998.

16. "Developing Antimicrobial Drugs--General Considerations for Clinical Trials"--issued July 1998.

17. "Catheter-Related Bloodstream Infections--Developing Antimicrobial Drugs for Treatment"--issued October 1999.

For information on the preceding 13 guidances (number 5 through 17), contact the Office of Antimicrobial Products in the Office of New Drugs in CDER.

18. "Labeling Over-the-Counter (OTC) Human Drug Products--Updating Labeling in ANDAs"--issued February 2001.

For information on the preceding guidance (number 18), contact the Office of Drug Evaluation IV in the Office of New Drugs in CDER.

19. "Inhalation Drug Products Packaged in Semipermeable Container Closure Systems"--issued July 2002.

20. "Listed Drugs, 30-Month Stays, and ANDAs and 505(b)(2) Applications Under Hatch-Waxman, as Amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003--Questions and Answers"--issued November 2004.

21. "Referencing Discontinued Labeling for Listed Drugs in Abbreviated New Drug Applications"--issued October 2000.

22. "Submission of Patent Information for Certain Old Antibiotics"--issued December 2008.

For information on the preceding four guidances (number 19 through 22), contact the Office of Pharmaceutical Science in CDER.

23. "Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act"--issued September 1999.

For information on the preceding guidance (number 23), contact the Pediatric and Maternal Health Staff in the Office of New Drugs in CDER.

III. Revision or Finalization of Guidances

In addition to identifying the first set of guidances for withdrawal, CDER also identified guidances for revision or finalization. CDER is in the process of developing a plan for their completion. Guidances for revision or finalization are specific to the following topics:

- Biopharmaceutics;
- Chemistry, manufacturing, and controls;
- Clinical pharmacology;
- Combination products;
- cGMP compliance;
- Development of antimicrobial drugs;
- Drug advertisements;
- Drug safety;
- Electronic submissions;
- Labeling;
- OTC products;
- Pharmacology and toxicology;
- Procedural guidances; and
- Radiopharmaceuticals.

IV. Maintaining Transparency

CDER would like to make this process as transparent as possible, consistent with the GGP regulation. As a result, CDER is issuing this notice announcing the initiative for draft guidance review, and listing the first group of guidances for withdrawal. CDER also maintains and regularly updates on its guidance Web site a list of new, revised, and withdrawn guidances

(at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm). Each year CDER also publishes on its guidance Web site a Guidance Agenda, which lists new draft and revised draft guidances planned for issuance in the given calendar year.

V. Comments

Interested persons may submit either electronic comments regarding Agency guidance documents to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

VI. Electronic Access

Persons with access to the Internet may obtain CDER guidance documents at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

Dated: August 2, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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