Guidance for Industry

Submission of Patent Information for Certain Old Antibiotics

DRAFT GUIDANCE

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For questions regarding this draft document contact (CDER) Mary Ann Holovac at 240-276-8971.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

Procedural

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I. INTRODUCTION

This guidance describes the Food and Drug Administration's (FDA's or the Agency's) current thinking on the implementation of section 4(b)(1) of the Q1 Program Supplemental Funding Act (Public Law 110-379) (the Q1 Act). It describes which sponsors of new drug applications (NDAs) must submit patent information to the Agency under section 4(b)(1) of the Q1 Act.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

Prior to the enactment of the Food and Drug Modernization Act of 1997 (FDAMA) on November 21, 1997, the FDA approved antibiotic drug marketing applications under section 507 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). Applications approved under section 507 were not subject to Title I of the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417)(Hatch-Waxman Amendments), which governs, among other things, patent listings and marketing exclusivity. Section 125 of FDAMA repealed section 507 and provided that applications for the marketing of antibiotic drugs that were approved under section 507, as in effect on the day before the date of enactment of FDAMA, were to be considered to be applications submitted, filed, and approved under section 505 of the FD&C Act (21 U.S.C. 355). However, section 125(d)(2) of FDAMA exempted from certain patent listing, patent certification, and marketing exclusivity provisions of sections 505(c) and (j) of the FD&C Act, marketing applications for drugs that contain an antibiotic that was the subject

[1] This guidance has been prepared by the Antibiotic Working Group in the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration.

of any marketing application received by the Secretary on or before November 20, 1997 (referred to in this guidance as an *old* antibiotic). In general, NDAs containing old antibiotics can be identified by NDA numbers that are in the 50,000 series.

Section 4 of the Q1 Act contains two subsections:

- The first (section 4(a)) amends section 505 of the FD&C Act to add substantive requirements regarding patent listing, patent certification, patent term extension, and exclusivity for NDAs that contain old antibiotics.
- The second (section 4(b)) contains deadlines for submitting certain patent information and patent certifications.

Section 4(a) of the Q1 Act amends section 505 of the FD&C Act by adding subsection (v), which establishes, among other things, certain conditions under which the patent listing, patent certification, and marketing exclusivity provisions of sections 505(c) and (j), and the patent term extension provisions of 35 U.S.C. 156 apply to marketing applications for drugs that contain an old antibiotic.

Section 4(b) of the Q1 Act (the transitional rules) provides for the submission of the patent information by certain sponsors of NDAs, the publication of such patent information by FDA, and the certification to such patents by applicants of pending abbreviated new drug applications (ANDAs) in order to be deemed "a first applicant" (as defined in section 505(j)(5)(B)(iv) of the FD&C Act), not later than 60, 90, and 120 days after enactment of the Q1 Act, respectively.

Specifically, section 4(b)(1) of the Q1 Act provides that:

> [w]ith respect to a patent issued on or before the enactment of this [Q1] Act, any patent information required to be filed with the Secretary of Health and Human Services under subsection (b)(1) or (c)(2) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) to be listed on a drug to which subsection (v)(1) of such section 505 (as added by this section) applies shall be filed with the Secretary not later than 60 days after the date of enactment of this [Q1] Act

This guidance describes the Agency's current thinking on the implementation of section 4(b)(1) of the Q1 Act and addresses which sponsors of NDAs must submit patent information to the Agency under section 4(b)(1). The guidance does not address FDA's interpretation of the scope of, and procedural requirements associated with, new section 505(v) of the FD&C Act, as added by the Q1 Act.

III. QUESTIONS AND ANSWERS

Q1: What are the relevant dates for implementation of section 4(b)(1) of the Q1 Act?

A1: The "date of the enactment of the Q1 Act" is October 8, 2008. Therefore, "before the date of the enactment of the Q1 Act" means on or before October 7, 2008. "Not later than

60 days after the date of enactment of the Q1 Act" means on or before December 5, 2008.[2]

Q2: Who must submit the patent information to FDA under section 4(b)(1) of the Q1 Act by December 5, 2008?

A2: The sponsor of an NDA approved on or before October 7, 2008, for a drug (including a combination drug) containing an antibiotic drug that was the subject of an application approved under section 507 of the FD&C Act (as in effect before November 21, 1997) must submit this patent information.[3]

For information on the submission of patent information, please consult the Agency's regulations governing the submission of patent information at 21 CFR 314.50(h) and 314.53.

[2] Section 4(b)(1) of the Q1 Act requires the submission of patent information to FDA "not later than sixty days after enactment of [the Q1 Act]." Sixty days after enactment falls on Sunday, December 7, 2008. Therefore, to be in compliance with this provision, sponsors must submit the patent information on or before the weekday preceding December 7, 2008, that is, on or before December 5, 2008.

[3] The application of section 4(b)(1) of the Q1 Act set forth in this guidance gives meaning to both section 505(v) of the FD&C Act, as added by section 4(a) of the Q1 Act, and the legislation's transitional rules at section 4(b). Section 4(b)(3) of the Q1 Act contemplates submission of patent certifications by applicants of pending ANDAs that reference drugs for which patent information must be listed under section 4(b)(1). By statute, ANDAs may reference only already approved drugs. *See* 21 U.S.C. 355(j)(2)(A). Therefore, the drugs referenced by these pending ANDAs (that is, drugs for which patent information was submitted under section 4(b)(1) of the Q1 Act) must be drugs that were approved on or before October 7, 2008. This approach is further supported by the requirement that FDA must, upon receipt of the patent information required to be submitted under 4(b)(1) of the Q1 Act, publish the information in the electronic version of FDA's *Approved Drug Products with Therapeutic Equivalents* (the Orange Book). Per section 505(j)(7) of the FD&C Act, the Orange Book includes only information about approved drugs. *See* section (4)(b)(2) of the Q1 Act.