AIPLA
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January 30, 2009

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**RE: FDA-2008-D-0609 - Draft Guidance for Industry on the Submission of Patent Information for Certain Old Antibiotics**

Dear Sir or Madam:

The American Intellectual Property Law Association ("AIPLA") submits the following comments concerning the FDA's implementation of Section 4 – "Incentives For The Development Of, And Access To, Certain Antibiotics" – of the "QI Program Supplemental Funding Act," Pub. Law No. 110-379 (Oct. 8, 2008) ("the QI Act"), which amended the Federal Food, Drug, and Cosmetic Act ("FDC Act") to add Section 505(v)– "Antibiotic Drugs Submitted Before November 21, 1997"– to make Hatch-Waxman benefits available for so-called "old" antibiotic drugs (i.e., antibiotic active ingredients included in an application submitted to FDA for review under the now-repealed FDC Act §507 prior to November 21, 1997), the date of enactment of the FDA Modernization Act ("FDAMA"). AIPLA is a national bar association constituted primarily of lawyers in private and corporate practice, in government service, and in the academic community, with more than 16,000 members. AIPLA represents a wide and diverse spectrum of individuals, companies and institutions involved directly or indirectly in the practice of patent, trademark, copyright, and unfair competition law, as well as other fields of law affecting intellectual property. AIPLA's members represent both owners and users of intellectual property. AIPLA's primary objectives are to aid in the improvement in laws relating to intellectual property and in their proper interpretation by the courts, and to provide legal education to the public and to its members on intellectual property issues.

The issues identified below do not directly concern FDA's Draft Guidance for Industry on the Submission of Patent Information for Certain Old Antibiotics. However, because FDA has not yet established a public docket requesting comment on the Agency's implementation of the QI Act, AIPLA is using the docket established by FDA with respect to the draft guidance as a vehicle to raise certain issues. AIPLA wishes to request that FDA establish a docket requesting public comment on QI Act implementation, similar to the docket FDA established after the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173 (Dec. 8, 2003) ("MMA"). See FDA, Generic Drug Issues; Request for Comments, 69 Fed. Reg. 9982 (Mar. 3, 2004).

**ISSUE #1 – THE AVAILABILTY OF A 30-MONTH STAY**

Under the Hatch-Waxman Amendments to the FDC Act, as amended by the MMA, a generic applicant that submits an Abbreviated New Drug Application ("ANDA") or 505(b)(2) application to FDA containing a Paragraph IV certification to an Orange Book-listed patent, and who is sued for patent infringement within the statutory 45-day period, is generally subject to a single 30-month stay of approval. Specifically, under FDC Act §§ 505(j)(5)(B)(iii) and 505(c)(3)(C), with respect to patents submitted to FDA for Orange Book listing on or after August 18, 2003, a 30-month stay of approval on an ANDA or 505(b)(2) application containing a Paragraph IV certification to the patent will ensue if: (1) the patent was submitted to FDA for Orange Book listing before the date that the ANDA or 505(b)(2) application (excluding an amendment or supplement) was submitted to FDA; and (2) the patent owner or NDA holder initiates a patent infringement action on the patent within 45 days of the date that it receives notice of the Paragraph IV certification. Thus, the amendments made to the FDC Act by the MMA preclude 30-month stays for those patents submitted to FDA for Orange Book listing on or after the date the ANDA or 505(b)(2) application was submitted (i.e., later listed patents).

FDA has explained in implementing this provision that:

> No 30-month stay of approval will apply if the patent was submitted to FDA *on or after* the date the ANDA or 505(b)(2) application with a paragraph IV certification to the patent was submitted. (Note that this is the case even if the later-submitted patent is the first listed patent to claim the drug described in the ANDA or 505(b)(2) application.) In addition, a 30-month stay will not ensue if litigation is initiated more than 45 days after the date that the patent owner or NDA holder receives notice of the certification.

FDA, Draft Guidance for Industry, Listed Drugs, 30-Month Stays, and Approval of 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, at 3 (Oct. 2004).

Section 4(b) of the QI Act creates certain transition provisions making the Orange Book patent listing provisions of the FDC Act applicable to NDAs covering old antibiotics approved on or before October 7, 2008. Other transition provisions require FDA to timely list such patent information in the Orange Book, and provide an opportunity for 180-day exclusivity for applicants with pending ANDAs. These transition provisions do not specifically address the availability of a 30-month stay. If FDA interprets the law such that the amendments made to the FDC Act by the MMA apply, then presumably no 30-month stay would apply to an ANDA applicant with a pending ANDA that amends such application to add a Paragraph IV certification to a newly-listed Orange Book patent. It is unclear, however, whether FDA intends to interpret the law in such manner, or whether FDA believes that the law could be interpreted to permit a 30-month stay under such circumstances, similar to pre-MMA version of the FDC Act.

## ISSUE #2 – THE AVAILABILITY OF ADDITIONAL EXCLUSIVITY

FDC Act § 505(v)(3)(A) – "Limitations — Exclusivities And Extensions" – as amended by the QI Act, states that FDC Act §§ 505(v)(1)(A) and (2)(A) "shall not be construed to entitle a drug that is the subject of an approved application described in [FDC Act §§ 505(v)(1)(B)(i) or (2)(B)(i)], as applicable, to any market exclusivities or patent extensions other than those exclusivities or extensions described in [FDC Act §§ 505(v)(1)(A) and (2)(A)]." FDC Act § 505(v)(1)(A) states that an application for an antibiotic drug submitted to FDA after October 8, 2008, and which antibiotic drug was the subject of an application approved by FDA under FDC Act § 507 before the enactment of FDAMA (i.e., an application for an antibiotic drug described at new FDC Act § 505(v)(1)(B)(i)) "shall be eligible for, with respect to the drug, the 3-year exclusivity period referred to under [FDC Act §§ 505(c)(3)(E)(iii)-(iv) and § 505(j)(5)(F)(iii)-(iv)], subject to the requirements of such clauses, as applicable." FDC Act § 505(v)(2)(A) states that an application for an antibiotic drug submitted to FDA after October 8, 2008, and which antibiotic drug was the subject of an application submitted under FDC Act § 507 but not approved by FDA before the enactment of FDAMA (i.e., an application for an old antibiotic drug that is a New Chemical Entity ("NCE")) described at new FDC Act § 505(v)(2)(B)(i)) "may elect to be eligible for, with respect to the drug," a period of 3-year exclusivity and a period of 5-year NCE exclusivity, or a Patent Term Extension ("PTE") under 35 U.S.C. § 156, subject to the requirements for obtaining such patent or non-patent exclusivity.

While FDC Act § 505(v)(3)(A) clearly places limits on how the new law can be interpreted, it is unclear whether it is also intended to limit the availability of non-patent market exclusivity under FDC Act § 505A (pediatric), and § 527 (orphan drug). There is very little legislative history on new FDC Act § 505(v); and the legislative history that does exist – primarily in Congressional Record statements from May 2007 by Senator Orrin Hatch (R-UT), the primary sponsor of the legislation – does not address Section 505(v)(3)(A).[1]

## ISSUE #3 – THE AVAILABILITY OF EXCLUSIVITY FOR OLD ANTIBIOTICS COVERED UNDER FDC ACT § 505(v)(2)

FDC Act § 505(v)(2)(A), as amended by the QI Act, states that an application for an antibiotic drug submitted to FDA after October 8, 2008, and which antibiotic drug was the subject of an application submitted under FDC Act § 507 but not approved by FDA before the enactment of FDAMA "may elect to be eligible for, with respect to the drug," a period of 3-year exclusivity "***and***" a period of 5-year NCE exclusivity, or a PTE under 35 U.S.C. § 156, subject to the requirements for obtaining such patent or non-patent exclusivity. FDC Act § 505(v)(2)(A) (emphasis added).

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[1] When Sen. Hatch introduced the legislation as an amendment to S. 1082 – "the Food and Drug Administration Revitalization Act," a precursor bill to the 2007 FDA Amendments Act ("FDAAA") – on May 2, 2007, the amendment included a provision similar to FDC Act § 505(v)(3)(A), which stated: "Paragraph (1) shall not be construed to entitle a drug that is the subject of an approved application described in paragraph 2 for any market exclusivities or patent extensions other than those exclusivities or extensions described in paragraph (1)." 153 Cong. Rec. S5511 (May 2, 2007).

The use of the conjunctive "and" in FDC Act § 505(v)(2)(A) is curious. It is unclear how a drug can simultaneously qualify for both 3-year "new use" exclusivity ***and*** 5-year NCE exclusivity. A drug product is considered an NCE entitled to 5-year exclusivity if it contains no previously approved active moiety, whereas a drug product is eligible for 3-year exclusivity if it contains a previously approved active moiety, is approved for a new condition of use, and otherwise meets the statutory and regulatory 3-year exclusivity criteria. Congress' use of the word "and" might have been intentional, such that an old antibiotic drug covered under FDC Act § 505(v)(2) can qualify for 3-year exclusivity for a new condition of use after an initial NDA approval that would qualify for 5-year exclusivity or a PTE – as an old antibiotic drug covered under FDC Act § 505(v)(2) does not appear to convert to an old antibiotic drug covered under FDC Act § 505(v)(1) once it is initially approved. Under this interpretation, 3-year and 5-year exclusivity are not granted simultaneously, but rather sequentially, provided the requirements for granting such exclusivity are met.

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Please contact me at 703-415-0780 if you have any questions concerning this submission. AIPLA looks forward to working with FDA as the Agency grapples with implementing the QI Act.

Sincerely,

Teresa Stanek Rea
President, AIPLA