

Apotex Inc. Comments re:

Federal Register Docket No. 2004D-0460

**Draft Guidance for Industry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**

Section II.E: 180-Day Exclusivity

What ANDAs are subject to the MMA's new 180 day exclusivity provisions?

In this section reference is made to the forfeiture provisions of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the "MMA"). We highly recommend that the specific application of these provisions by the FDA be described in the guidance in a question-and-answer format to address each of the possible forfeiture events, including information on how the following issues will be addressed:

- Since the status of an ANDA application is not publicly available, there are several forfeiture events which may impact the first applicant's eligibility for 180-day exclusivity, but of which other ANDA applicants would have no knowledge. How will the FDA monitor the first applicant's activities to determine if and when a forfeiture event takes place and how and will the FDA notify other ANDA applicants that the event has occurred?
- In the event that a 180-day exclusivity period is lost by the "first applicant" as the result of a specific forfeiture event, what is the timeframe within which the FDA will issue final approval on ANDAs with Tentative Approval for the same drug product?

Declaratory Judgment Action and Counterclaims

The MMA includes provisions to allow an ANDA applicant to bring a declaratory judgment action against the listed drug NDA or patent holder to seek a finding that the patent is invalid or will not be infringed with two conditions as described in the MMA. We recommend that the FDA's role in this process be described in the guidance, including information on the following:

- Is the ANDA applicant required to notify the FDA if and when a declaratory judgment has been filed? If so, how?
- How and when should an ANDA applicant notify the FDA of the outcome of a declaratory judgment action?

- What are the specific conditions under which an ANDA application will be approved further to the decision in favor of the ANDA applicant in a declaratory judgment action?
- In the event that an ANDA applicant brings a counterclaim against the listed drug NDA or patent holder further to infringement action by the latter, and the ANDA applicant is successful, will the FDA notify other ANDA applicants for the same drug product of the changes to the patent(s) prior to the next Orange Book revision? If so, how and within what timeframe?