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New Requirements for Citizen Petitions Concerning ANDA's and 505(b)(2) Applications

On September 27, 2007, President Bush signed into law the Food and Drug Administration Amendments Act of 2007 (FDAAA), which amended the Federal Food, Drug, and Cosmetic Act (FFDCA) to include provisions regarding citizen petitions and petitions for stay of agency action.

- **Conditions for Delay in Approval.** Requests for FDA to take any form of action relating to a pending 505(b)(2) application or ANDA may not delay approval of the subject 505(b)(2) application or ANDA unless: (1) the request is made in writing in the form of a citizen petition or petition for stay of agency action pursuant to 21 C.F.R. §§ 10.30 or 10.35, AND (2) the agency determines that “a delay is necessary to protect the public health.” If FDA determines that a delay is warranted, the applicant must be notified in writing within 30 days of the determination.
- **Primary Purpose of Delaying Approval.** The legislation authorizes FDA to deny a petition if the agency determines the petition (or a supplement thereto) was submitted with the primary purpose of delaying approval of a 505(b)(2) application or ANDA and the petition does not raise valid scientific or regulatory issues. FDA is permitted, but not required, to issue guidance describing the factors that will be used to determine if a submission has been made for the primary purpose of delaying approval.
- **180 Day Action Requirement.** FDA must take final agency action on such a petition within 180 days of submission. The 180 day period may not be extended for any reason. FDA will be considered to have taken final agency action on a petition if it issues a substantive decision or if the 180 day period expires without issuance of a substantive decision. Any lawsuit brought against FDA concerning any issue raised in a petition before FDA issues a substantive decision or the 180 day period has lapsed without issuance of a substantive decision shall be dismissed for failure to exhaust administrative remedies.
- **Required Certification.** In an effort to ensure petitions are submitted in a timely manner, the legislation requires petitions (and supplements thereto) to be accompanied by a certification including a statement of the date on which the party on whose behalf the petition is filed became aware of the information on which the petition (or supplement) is based. The



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certification must also identify the persons/organizations paying the petitioner to file the petition.

- **Extension of 30 Month Period.** If approval of an ANDA eligible for 180 day exclusivity was delayed as a result of such a petition, the applicant will not be penalized by the delay for purposes of determining whether a forfeiture event has occurred for failure to obtain tentative approval within 30 months after filing of the ANDA (Section 505(j)(5)(D)(i)(IV)). Specifically, the 30 month period will be extended by a period of time equal to the time the petition was pending before the agency, regardless of whether the petition is granted or denied.
- **Reporting to Congress.** FDA must submit an annual report to Congress detailing any delays in approval of 505(b)(2) applications or ANDAs resulting from petitions. In addition, FDA must submit a report to Congress within one year suggesting methods to encourage the early submission of these types of petitions.
- **Exemptions.** The legislation specifically exempts: (1) petitions that relate solely to the timing of the approval of an application under the 180 day exclusivity provisions (Section 505(j)(5)(B)(iv)), and (2) petitions filed by a sponsor pertaining to the sponsor's own application.