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FDA Proposed Rule Addresses Citizen Petitions Involving ANDAs and Section 505(b)(2) New Drug Applications

On January 3, 2012, the Food and Drug Administration (FDA) issued a proposed rule to amend the regulations on Citizen Petitions and Petitions for Stay of Action (collectively referred to as Petitions), relating to requests for the FDA to take action on a pending drug application submitted under section 505(b)(2) or (j) of the Federal Food, Drug, and Cosmetic Act (FDC Act).[1] The proposed rule would implement section 505(q) of the FDC Act, 21 U.S.C. § 355(q), which was added as part of the Food and Drug Administration Amendments Act of 2007 in response to Congressional concerns that petitions submitted late in the drug application review process were resulting in the improper delay of drug approvals.

The proposed rule would add a new subsection to the regulations,[2] which would apply to all Petitions that request any form of agency action which could, if taken, result in a delay of an abbreviated new drug application or a new drug application submitted under Section 505(b)(2). The proposed rule would also make minor amendments to other existing regulatory provisions. The proposed rule includes the following items, in addition to other minor technical changes to 21 C.F.R. §§ 10.20 (submission of documents to the FDA's Division of Dockets Management), 10.30 (Citizen Petitions), and 10.35 (Administrative Stay of Action):

- Clarification that the date of submission for such Petitions is considered *the date of receipt* by the Division of Dockets Management, for the purpose of starting the 180-day time clock for the FDA to respond to a petition;
- Codification of specific language relating to certification[3] and verification[4] requirements, which will also require the petitioner to identify the dates (i.e., month, day and year) that the information serving as the basis for the action first became known to the parties involved;

1 77 *Fed. Reg.* 25
2 21 C.F.R. § 10.31
3 The certification proposal, to be used with the submission of Petitions, would require, in part, that the petitioner believes the information is complete, includes any unfavorable information known to the petitioner, and reports any compensation to submit the Petition.
4 The verification proposal, to be used for submissions of supplemental information or comments on Petitions, would require, among other things, that the petitioner certify that submission of the document was not intentionally delayed and report any compensation received to submit the document.

- Petitioner for a stay of action may supplement, amend, or withdraw a petition for stay of action, similar to what is allowed for Citizen Petitions; and
- Addition of an express statement that the FDA Commissioner may dismiss any petition as moot.

The FDA will accept comments on the proposed rule until April 2, 2012.