



August 4, 1998

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Docket Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Drive, Room 1-23
Rockville, MD 20857

RE: Docket #98D-0514 "Guidance for Industry: ANDAs: Impurities in Drug Substances"

To Whom It May Concern:

The Perrigo Company hereby requests a 120-day extension of the comment period for the above referenced document. According to the publication, comments were to be submitted by September 22, 1998.

Perrigo is the nation's largest private label manufacturer of over-the-counter (OTC) drug products. As such, Perrigo produces OTC drug products for numerous chain drug stores and supermarkets. Perrigo manufactures OTC products which are described in Abbreviated New Drug Applications (ANDAs) and are subject to FDA's review and approval pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act.

In the July 24, 1998 Federal Register, Volume 63, No. 142, an announcement of a Draft Guideline entitled "Guidance for Industry: ANDAs: Impurities in Drug Substances" was published. With this Notice, the Agency has indicated a 60-day comment period, which closes September 22, 1998.

Due to the importance of this Guidance and the recent issuance of several other guidances that also require review and comment, Perrigo respectfully requests an extension to the comment period. Perrigo would suggest an extension of 120 days with a closing period of January 22, 1999. This extension will give a more reasonable amount of time for Perrigo and the entire industry to do a complete and thorough review and comment on this proposal.

We appreciate your consideration and response at your earliest convenience.

Sincerely,

PERRIGO COMPANY

David A. Jespersen
Director, Technical Services

cc: Bill Bradley, NDMA
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Robert Milanese, NAPM

98D-0514

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