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Certifier	M-Bell

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D-1267]

Guidance for Industry on NDAs: Impurities in Drug Substances; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "NDAs: Impurities in Drug Substances." This document recommends that applicants submitting new drug applications (NDA's) and holders of supporting Type II drug master files (DMF's) for drug substances not considered new drug substances refer to the guidance for industry on reporting drug substance impurities in the International Conference on Harmonisation (ICH) guidance document entitled "Q3A Impurities in New Drug Substances."

DATES: Submit written comments on agency guidances at any time.

ADDRESSES: Copies of this guidance for industry are available on the Internet at <http://www.fda.gov/cder/guidance/index.htm>. Submit written requests for single copies of this guidance to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Eric P. Duffy, Center for Drug Evaluation and Research (HFD-150), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5765.

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SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled "NDAs: Impurities in Drug Substances." Although ICH "Q3A Impurities in New Drug Substances," which was published in the **Federal Register** on January 4, 1996 (61 FR 372), provided guidance to industry on the reporting, identification, and qualification of impurities in new drug substances produced by chemical syntheses, FDA believes that the guidance provided in ICH Q3A should also be considered when evaluating drug substances produced by chemical syntheses that are not considered new drug substances. FDA recommends that applicants preparing NDA's and holders preparing Type II DMF's refer to the information contained in that ICH document.

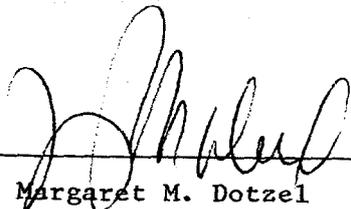
In the **Federal Register** of January 21, 1999 (64 FR 3303), FDA announced the availability of a draft version of this guidance. The January 1999 document gave interested persons an opportunity to submit comments through April 21, 1999. All comments received during the comment period have been carefully reviewed and the guidance has been revised, where appropriate.

This level 1 guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The guidance represents the agency's current thinking on reporting impurities in drug substances for certain NDA's and DMF's. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes, regulations, or both.

Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number

found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 2/15/00
February 15, 2000

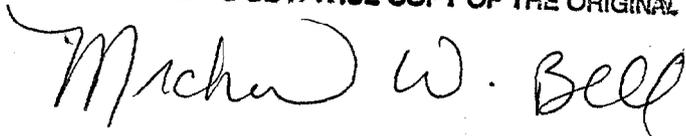


Margaret M. Dotzel
Acting Associate Commissioner for Policy

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