

This guidance is being issued as a level 1 guidance consistent with our good guidance practices regulation (21 CFR 10.115). It is being implemented immediately without prior public comment because we believe it is in the interest of the public health to communicate this information to the public as quickly as possible. However, we welcome comments on the guidance, and if comments are submitted, we will review them and revise the guidance if appropriate. The guidance represents our current thinking on issues associated with the submission of NDAs for Ca-DTPA and Zn-DTPA drug products. 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 and regulations.

#### B. Comments

Interested persons may, at any time, submit written comments on the guidance to the Division of Dockets Management (see **ADDRESSES**). Two copies of any mailed comments are to be submitted except that individuals may submit one copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. The document and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

#### C. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

#### V. Published Literature on the Safety and Effectiveness of Ca-DTPA and Zn-DTPA

The published literature we have relied on in making the determinations regarding Ca-DTPA and Zn-DTPA contained in this notice is listed in this section of this document. Copies of the published literature will be on display in the Division of Dockets Management (see **ADDRESSES**) and can be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site address, but we are not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

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13. Calder, S. E., C. W. Mays, G. N. Taylor, et al., "Zn-DTPA Safety in the Mouse Fetus," *Health Physics*, 36:524-526, 1978.

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