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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0111]

Guidance for Federal Agencies and State and Local Governments; Potassium Iodide Shelf Life Extension; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for Federal agencies and State and local governments entitled "Potassium Iodide Tablets Shelf Life Extension." This document is intended to provide guidance to Federal agencies and to State and local governments on testing to extend the shelf life of stockpiled potassium iodide (KI) tablets.

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

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), 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 Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.* See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

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FOR FURTHER INFORMATION CONTACT: Richard Adams, Center for Drug Evaluation and Research (HFD–643), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–5849.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for Federal agencies and State and local governments entitled "Potassium Iodide Tablets Shelf Life Extension." This guidance is intended to provide Federal agencies and State and local governments with information on testing to extend the shelf life of stockpiled KI tablets. The agency has developed this document in response to several State inquiries on this topic.

On December 11, 2001 (66 FR 64046), FDA provided guidance on the safe and effective use of KI tablets as an adjunct to other public health protective measures in the event that radioactive iodine is released into the environment. The guidance entitled "Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies" updated FDA's 1982 recommendations for the use of KI tablets to reduce the risk of thyroid cancer in radiation emergencies involving the release of radioactive iodine. The recommendations in that guidance addressed KI dosage and the projected radiation exposure at which the drug should be used.

On April 2, 2003 (68 FR 16063), FDA made available a draft guidance entitled "Potassium Iodide Tablets Shelf Life Extension." This guidance discussed FDA recommendations on the testing for shelf life extensions, the qualifications of laboratories suitable to conduct the tests, and issues regarding notification of holders of stockpiled KI tablets and end users about changes to batch shelf life once testing has been successfully conducted. The comment

period for that draft guidance closed on June 2, 2003. Although the agency received no written comments on the draft guidance, we (FDA) have revised the guidance slightly to recommend confirmatory testing after 2 years, monitoring for discoloration and recordkeeping.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on this topic. 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 applicable statues and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance at any time. Two copies of mailed 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

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

Dated: 2/27/00

February 28, 2004.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

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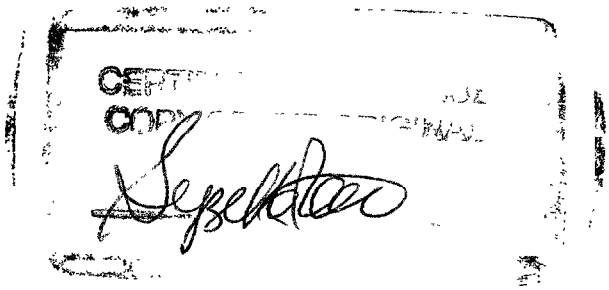
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