

**SUPPLEMENTARY INFORMATION:** In FR Doc. 01-1713, appearing on page 6624 in the **Federal Register** of January 22, 2001, the following corrections are made:

1. On page 6625, in the first column, in the last line of the first paragraph, the Internet address is corrected to read "http://www.iom.edu/fcc."

2. On the same page beginning in the same column, the formatting of all the entries listed under **I. Proposed New Monographs** and under **II. Current Monographs to Which the Committee Proposes to Make Revisions** is corrected to read:

#### **I. Proposed New Monographs**

##### Flavor Chemicals

Acetaldehyde Diethyl Acetal  
2-Acetyl Thiazole  
Allyl Phenoxy Acetate  
Allyl Propionate  
Borneol  
Butyl 2-Methyl Butyrate  
2-sec-Butyl Cyclohexanone  
Diphenyl Ether  
d-Fenchone  
Fenchyl Alcohol  
Furfuryl Alcohol  
2-Furyl Methyl Ketone  
Salatrim  
Soy Protein Concentrate

#### **II. Current Monographs to Which the Committee Proposes to Make Revisions**

Ammonium Phosphate, Monobasic (fluoride test corrected)  
Carmine (description and assay test revised)  
Enzyme Preparations (classifications and reactions added for  $\alpha$ -Acetolactatedecarboxylase;  
Aminopeptidase, Leucine; and Lysozyme) Flavor Chemicals  
Cinnamic Acid (solubility in alcohol revised)  
d-Dihydrocarvone (solubility in alcohol revised)  
2-Heptanone (specific gravity revised)  
Hexyl Isovalerate (solubility in alcohol revised)  
Isoamyl Benzoate (solubility in alcohol revised)  
Nerolidol (assay revised)  
(Z)-6-Nonen-1-ol (refractive index revised)  $\alpha$ -Pinene (angular rotation revised) 2-Undecenol (specific gravity revised)  
Potassium Phosphate, Monobasic (fluoride test corrected)  
Potassium Phosphate, Tribasic (fluoride test corrected)  
Potassium Pyrophosphate (fluoride test corrected)  
Potassium Tripolyphosphate (fluoride test corrected)  
Sodium Acid Pyrophosphate (fluoride test corrected)  
Sodium Metaphosphate, Insoluble (fluoride test corrected)

Sodium Phosphate, Dibasic (fluoride test corrected)  
Sodium Phosphate, Monobasic (fluoride test corrected)  
Sodium Polyphosphate, Glassy (fluoride test corrected)  
Sodium Potassium Tripolyphosphate (fluoride test corrected)  
Sodium Trimetaphosphate (fluoride test corrected)  
Sodium Tripolyphosphate (fluoride test corrected)

3. On page 6625, in the third column, the last sentence is corrected to read: "Copies of the proposed changes may also be obtained through the Internet at <http://www.iom.edu/fcc>."

Dated: February 2, 2001.

**L. Robert Lake,**

*Director of Regulations and Policy, Center for Food Safety and Applied Nutrition.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket No. 00D-1681]

#### **Draft Guidance on Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies; Availability; Extension of Comment Period**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is extending to April 30, 2001, the comment period for the draft guidance entitled "Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies" that appeared in the **Federal Register** of January 4, 2001 (66 FR 801). FDA is taking this action in response to a request for an extension.

**DATES:** Submit written comments on the draft guidance by April 30, 2001. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Copies of this draft guidance are available on the Internet at <http://www.fda.gov/cder/guidance/index.htm>. Submit written requests for single copies of the draft 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 the office in processing your request. Submit written comments to the

Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Requests and comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Rose E. Cunningham, Executive Operations (HFD-06), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-6779.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of January 4, 2001 (66 FR 801), FDA published a notice announcing the availability of a draft guidance document entitled "Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies." This draft guidance updates the notice of availability entitled "Potassium Iodide as a Thyroid-Blocking Agent In a Radiation Emergency: Final Recommendations On Use," published in the **Federal Register** of June 29, 1982 (47 FR 28158). In this draft guidance, FDA maintains its position that potassium iodide is a safe and effective means by which to prevent radioiodine uptake by the thyroid gland, under certain specified conditions of use, and thus to lessen the risk of thyroid cancer in the event of a radiation emergency.

FDA received an e-mail request, dated January 4, 2001, requesting that the agency extend the comment period on the draft guidance by 60 days, allowing 90 days for comments. Because the draft guidance introduces several new recommendations, the agency has decided to extend the comment period on the draft guidance to April 30, 2001, to allow the public more time to review and comment on its contents.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance document by April 30, 2001. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. The draft guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 2, 2001.

**Ann M. Witt,**

*Acting Associate Commissioner for Policy.*

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