In addition to the product listing information required on Form FDA 2657, FDA may also require, under § 207.31, a copy of all advertisements and a quantitative listing of all ingredients for each listed drug or biological product not subject to an approved application or license; the basis for a determination, by the establishment, that a listed drug or biological product is not subject to marketing or licensing approval requirements; and a list of certain drugs or biological products containing a particular ingredient. FDA may also request, but not require, the submission of a qualitative listing of the inactive ingredients for all listed drugs or biological products, and a quantitative listing of the active ingredients for all listed drugs or biological products subject to an approved application or license.

Under § 207.30, establishments must update their product listing information by using Form FDA 2657 and/or Form FDA 2658 every June and December or, at the discretion of the establishment, when any change occurs. These updates must include the following information: (1) A listing of all drug or biological products introduced for commercial distribution that have not been included in any previously submitted list, (2) all drug or biological products formerly listed for which commercial distribution has been discontinued, (3) all drug or biological products for which a notice of discontinuance was submitted and for which commercial distribution has been resumed, and (4) any material change in any information previously submitted. No update is required if no changes have occurred since the previously submitted list.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

Reporting	No. of Respondents	No. of Respones per Respondent	Annual Frequency per Response	Total Annual Responses	Hours per Response
(1) Form FDA–2656 Registration of Drug Establishment					
21 CFR 207.21, 207.22, 207.25, 207.26, and 207.40	15,802	.34	5,438	.5	2,719
(2) Form FDA–2656e Annual Update of Drug Establishment					
21 CFR 207.21, 207.22, 207.25, 207.26, and 207.40	7,226	1	7,226	.5	3,613
(3) Form FDA–2657 Drug Product Listing					
21 CFR 207.21, 207.22, 207.25, 207.30, 207.31, and 207.40	14,381	2.80	40,270	.5	20,135
(4) Form FDA–2658 Registered Establishments' Report of Private Label Distributors					
21 CFR 207.21, 207.22, 207.25, 207.30, and 207.31	6,221	2.14	13,289	.5	6,645
Total Reporting Burden					33,112

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

In the **Federal Register** of November 2, 2000 (65 FR 65858), the agency requested comments on the proposed collections of information. The agency received one comment on the 60-day notice. The comment recommended that FDA eliminate the requirement to send a representative label and/or carton with each Form FDA 2657 and 2658, and that, instead, the labeling would be available and submitted to FDA upon request.

FDA appreciates the recommendation concerning labeling submissions. However, the comment is beyond the scope of the November 2, 2000, notice. That notice provided an opportunity for public comment on the agency's estimates of the burden resulting from the information collection requirements imposed by part 207. In the **Federal Register** of November 30, 2000 (65 FR 73798), FDA announced as part of the semiannual regulatory agenda that it intends to publish a proposed rule to revise part 207 to clarify the requirements for registration and listing and to consolidate and reorganize the regulations. The proposal would also require the electronic submission of establishment registration and product listing information. It would be more appropriate to submit the comment to that proposed rule after it publishes in the **Federal Register**.

Dated: February 5, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 01–3414 Filed 2–8–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1685]

New Food Chemicals Codex Monographs, Revisions of Certain Food Chemicals Codex Monographs, a New General Test Procedure, and Revisions to a Policy; Opportunity for Public Comment; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice document that published in the **Federal Register** of January 22, 2001 (66 FR 6624). The notice announced an opportunity for public comment on proposed new Food Chemicals Codex specification monographs, proposed changes to certain Food Chemicals Codex specification monographs, a proposed new general test procedure, and proposed changes to a policy in the fourth edition. The notice was published with some inadvertent errors. This document corrects those errors.

DATES: Submit written comments by March 8, 2001. (The committee advises that comments received after this date may not be considered for the third supplement to the fourth edition. Comments received too late for consideration for the third supplement will be considered for later supplements or for a new edition of the Food Chemicals Codex.)

FOR FURTHER INFORMATION CONTACT: Paul M. Kuznesof, Division of Product Manufacture and Use (HFS–246), Office of Premarket Approval, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3009.

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 α-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.

[FR Doc. 01–3347 Filed 2–8–01; 8:45 am]

BILLING CODE 4160–01–F

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.

[FR Doc. 01–3417 Filed 2–8–01; 8:45 am]

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