Dated: March 20, 1997.

**Ida M. Ustad,**

*Deputy Associate Administrator, Office of Acquisition Policy.*

[FR Doc. 97–7939 Filed 3–27–97; 8:45 am]

**BILLING CODE 6820–61–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 97N–0026]**

### New Monographs and Revisions of Certain Food Chemicals Codex Monographs; Opportunity for Public Comment

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on pending changes to certain Food Chemicals Codex specification monographs in the fourth edition and on proposed new specification monographs. New monographs for certain substances used as food ingredients and additions, revisions, and corrections to current monographs are being prepared by the National Academy of Sciences/Institute of Medicine (NAS/IOM) Committee on Food Chemicals Codex (the committee). This material is expected to be presented in the next publication of the Food Chemicals Codex (the first supplement to the fourth edition), scheduled for publication in late summer 1997.

**DATES:** Written comments by May 12, 1997. (The committee advises that comments received after this date may not be considered for the first supplement to the fourth edition. Comments received too late for consideration for the first supplement will be considered for later supplements.)

**ADDRESSES:** Submit written comments and supporting data and documentation to the NAS/IOM Committee on Food Chemicals Codex, National Academy of Sciences, 2101 Constitution Ave. NW., Washington, DC 20418. Copies of the new monographs and proposed revisions to current monographs may be obtained upon written request from NAS (address above) or may be examined at the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Requests for copies should specify the monographs desired by name. New and revised monographs may also be obtained through the Internet at http://www2.nas.edu/codex.

**FOR FURTHER INFORMATION CONTACT:** Fatima N. Johnson, Committee on Food Chemicals Codex, Food and Nutrition Board, National Academy of Sciences, 2101 Constitution Ave. NW., Washington, DC 20418, 202–334–2580; or Paul M. Kuznesof, Center for Food Safety and Applied Nutrition (HFS–247), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3009.

**SUPPLEMENTARY INFORMATION:** By contract with NAS/IOM, FDA supports the preparation of the Food Chemicals Codex, a compendium of specification monographs for substances used as food ingredients. Before any specifications are included in a Food Chemicals Codex publication, public announcement is made in the **Federal Register**. All interested parties are invited to comment and to make suggestions for consideration. Suggestions should be accompanied by supporting data or other documentation to facilitate and expedite review by the committee.

In the **Federal Register** of December 3, 1996 (61 FR 64098), FDA last announced that the committee was considering additional new monographs and a number of monograph revisions for inclusion in the first supplement to the fourth edition of the Food Chemicals Codex, which is scheduled for publication in late summer, 1997. The fourth edition of the Food Chemicals Codex was released by the National Academy Press (NAP) in March 1996. It is now available for sale from NAP (1–800–624–6242; 202–334–3313; FAX 202–334–2451; Internet http://www.nap.edu) 2101 Constitution Ave. NW., Lockbox 285, Washington, DC 20055.

FDA now gives notice that the committee is soliciting comments and information on additional proposed new monographs and proposed changes to certain current monographs. These new monographs and changes are also expected to be published in the first supplement to the fourth edition of the Food Chemicals Codex. Copies of the proposed new monographs and revisions to current monographs may be obtained upon written request from NAS at the address listed above or through the internet at http://www2.nas.edu/codex.

FDA emphasizes, however, that it will not consider adopting and incorporating any of the committee's new monographs or monograph revisions into FDA regulations without ample opportunity for public comment. If FDA decides to propose the adoption of new monographs and changes that have received final approval of the committee, it will announce its intention and provide an opportunity for public comment in the **Federal Register**.

The committee invites comments and suggestions by all interested parties on specifications to be included in the proposed new monographs (3) and revisions of current monographs (8) listed below:

#### I. Proposed New Monographs

Manganese Citrate
Olestra
Vitamin K

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

Acid Hydrolysates of Proteins (add new limit tests for 3-chloropropane-1,2-diol and 1,3- dichloro-2-propanol; correct limit tests for potassium and sodium)
Calcium Chloride (change description)
Calcium Chloride Solution (reduce lead limit)
Glycerol Ester of Partially Dimerized Rosin (change softening point test procedure)
Hydroxylated Lecithin (reduce heavy metals and lead limits)
Iron, Reduced (revise arsenic specification)
Lecithin (change description, add labeling requirement, increase acid value limit, reduce heavy metals and lead limits, and revise peroxide value limit for enzyme-modified material)
Phosphoric Acid (increase heavy metals limit, add lead requirement)

Interested persons may, on or before May 12, 1997, submit to NAS written comments regarding the monographs listed in this notice. Timely submission will ensure that comments are considered for the first supplement to the fourth edition of the Food Chemicals Codex. Comments received after this date may not be considered for the first supplement, but will be considered for subsequent supplements. Those wishing to make comments are encouraged to submit supporting data and documentation with their comments. Two copies of any comments regarding the monographs listed in this notice are to be submitted to NAS (address above). Comments and supporting data or documentation are to be identified with the docket number found in brackets in the heading of this document and each submission should include the statement that it is in response to this **Federal Register** notice. NAS will

forward a copy of each comment to the Dockets Management Branch (address above). Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 20, 1997.

**Fred R. Shank,**

*Director, Center for Food Safety and Applied Nutrition.*

[FR Doc. 97–7836 Filed 3–27–97; 8:45 am]

**BILLING CODE 4160–01–F**

---

**[Docket No. 95P–0110]**

## Prescription Drug Advertising and Promotional Labeling; Development and Use of FDA Guidance Documents; Request for Comments

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

**ACTION:** Notice; request for comments.

**SUMMARY:** As part of ongoing efforts initiated by the Food and Drug Administration (FDA) in March 1996 to ensure meaningful public participation in the guidance document development process, FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC) is requesting public comment on guidance documents relating to prescription drug advertising and labeling. DDMAC has identified three general types of guidance documents on which it is seeking public comment. Specifically, DDMAC is requesting public comment on the rescission of guidances identified by DDMAC as obsolete, the revision and reissuance of DDMAC guidances that address current issues, and currently proposed guidance documents and suggestions of topics for new guidances that DDMAC may develop.

**DATES:** Written comments by June 26, 1997.

**ADDRESSES:** Submit written requests for copies of the guidances under review by DDMAC to the Freedom of Information Staff (HFI–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Submit written comments on the guidances or related issues to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Two copies of any comments are to be submitted, except that individuals may submit one. Comments should be identified with the docket number found in brackets in the heading of this document. Copies of the guidances under review by DDMAC are available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

**FOR FURTHER INFORMATION CONTACT:** Melissa M. Moncavage, Center for Drug Evaluation and Research (HFD–40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2828, e–mail: ''moncavage@cder.fda.gov.''

**SUPPLEMENTARY INFORMATION:** Issues relating to FDA's development and issuance of guidance documents were raised in a citizen petition submitted by the Indiana Medical Devices Manufacturers Council, Inc. (IMDMC) (see Docket No. 95P–0110). The IMDMC petition requested that FDA control the initiation, development, and issuance of guidance documents by written procedures that ensure the appropriate level of meaningful public participation. In response to the petition, FDA agreed to take steps to improve the agency's guidance document procedures.

In the **Federal Register** of March 7, 1996 (61 FR 9181), FDA published a notice that set forth its proposal on how best to improve its guidance document procedures and solicited comment on these and additional ideas for improvement (March 1996 notice). On April 26, 1996, the agency held a public meeting to discuss these issues further. The comment period for the March 7 notice closed on June 5, 1996. In the **Federal Register** of February 27, 1997 (62 FR 8961), FDA published a notice explaining how the agency will proceed in the future with guidance document development, issuance, and use. The notice included the agency document entitled ''Good Guidance Practices'' (the GGP's document), which sets forth the agency's policies and procedures for developing, issuing, and using guidance documents.

In the GGP's document, the agency defines ''guidance documents'' to include documents prepared for FDA staff, applicants and sponsors, and the public that: (1) Relate to the processing, content, and evaluation and approval of submissions; (2) relate to the design, production, manufacturing, and testing of regulated products; (3) describe the agency's policy and regulatory approach to an issue; or (4) establish inspection and enforcement policies and procedures. ''Guidance documents'' do not include documents relating to internal FDA procedures, agency reports, general information documents provided to consumers, speeches, journal articles and editorials, media interviews, press materials, warning letters, or other communications directed to individual persons or firms.

Guidance documents do not create or confer any rights for or on any person and do not operate to bind FDA or the public. Rather, they explain the agency's current thinking on a certain subject. However, a company affected by a guidance may use an alternative approach if the alternative approach satisfies the requirements of the applicable statute, regulations, or both. A guidance document cannot itself be the basis for an enforcement action.

FDA has adopted a two-level approach to the development of guidance documents. The procedures for developing a guidance document will depend on whether that guidance document is a ''level 1'' guidance or a ''level 2'' guidance. Level 1 guidance documents generally include guidance that sets forth first interpretations of statutory or regulatory requirements, changes in interpretation or policy that are of more than a minor nature, unusually complex scientific issues, or highly controversial issues. Level 1 guidance documents are directed primarily to applicants or sponsors or other members of the regulated industry. Level 2 guidance documents include all other guidance documents. In general, the agency will solicit public comment during the development of level 1 guidance documents. For level 2 guidance documents, the agency may choose to solicit comment before implementing a guidance, but in general an opportunity for public comment will be provided upon issuance of the guidance document. (See FDA GGP's.)

The agency also is making efforts to keep the public up to date on the status of agency guidance development and to provide the public an opportunity to suggest possible topics for document development or revision.

DDMAC guidances on achieving compliance with the prescription drug advertising and labeling statutes and regulations have been issued to the pharmaceutical industry since 1970 in various forms, often as letters or guidance papers. As a result of FDA's GGP effort, DDMAC has decided to reissue its guidance documents in a standardized format and grouped by common topic, such as content, format, class of drugs, or how to interact with DDMAC. To that end, DDMAC is undertaking a review of all such guidances to determine the following: (1) Which guidances are obsolete; (2) which guidances address current issues, but may need revision; and (3) whether there are new topics on which DDMAC should develop guidance documents. Once the guidance review process is completed, new and reissued DDMAC guidances will be made available, in