Board of Governors of the Federal Reserve System, April 2, 1998.

William W. Wiles,

Secretary of the Board.

[FR Doc. 98–9072 Filed 4–6–98; 8:45 am]

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FEDERAL RESERVE SYSTEM

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Board of Governors of the Federal Reserve System.

TIME AND DATE: 11:00 a.m., Monday, April 13, 1998.

PLACE: Marriner S. Eccles Federal Reserve Board Building, 20th and C Streets, NW., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Joseph R. Coyne, Assistant to the Board; 202–452–3204.

SUPPLEMENTARY INFORMATION: You may call 202–452–3206 beginning at approximately 5 p.m. two business days before the meeting for a recorded announcement of bank and bank holding company applications scheduled for the meeting; or you may contact the Board's Wed site at http://www.bog.frb.fed.us for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Dated: April 3, 1998.

William W. Wiles,

Secretary of the Board.

[FR Doc. 98–9268 Filed 4–3–98; 3:48 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0182]

Bulk Drug Substances To Be Used in Pharmacy Compounding; Request for Nominations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for nominations.

SUMMARY: The Food and Drug Administration (FDA) is preparing to develop a list of bulk drug substances (bulk drugs) that may be used in pharmacy compounding that do not have a United States Pharmacopeia (USP) or National Formulary (NF) monograph and are not components of approved drugs. FDA is taking this action in accordance with provisions in the Food and Drug Administration Modernization Act of 1997 (FDAMA). To identify candidates for this bulk drugs list, FDA is encouraging interested groups and individuals to nominate specific bulk drug substances and is describing the information that should be provided to the agency in support of each nomination.

DATES: Nominations must be received by June 8, 1998, to receive consideration for inclusion on the bulk drugs list. Nominations received after this date will receive consideration for subsequent amendments to the list.

ADDRESSES: Send nominations to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Robert J. Tonelli, Center for Drug Evaluation and Research (HFD–332), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–0101.

SUPPLEMENTARY INFORMATION: President Clinton signed FDAMA (Pub. L. 105–115) into law on November 21, 1997. One of the issues addressed in this new legislation is the applicability of the Federal Food, Drug, and Cosmetic Act (the act) to the practice of pharmacy compounding. Compounding involves a process whereby a pharmacist or physician combines, mixes, or alters ingredients to create a customized medication for an individual patient. Section 127 of FDAMA, which adds section 503A to the act (21 U.S.C. 353a), describes the circumstances under which compounded drugs qualify for exemptions from certain adulteration, misbranding, and new drug provisions of the act. Section 127 becomes effective 1 year from the date of the FDAMA's enactment (section 503A(b) of the act).

Section 127 contains several restrictions regarding the bulk drug substances[1] that may be used as ingredients in compounding and still qualify for the applicable exemptions. It provides, among other things, that such substances must comply with the standards of an applicable USP or NF monograph, if one exists, and the USP chapter on pharmacy compounding; if a monograph does not exist, they must be components of drugs approved by FDA; and if neither of those criteria are satisfied, they must appear on a list that FDA develops and issues through regulations (section 503A(b)(1)(A)(i)(I) through (b)(1)(A)(i)(III) of the act).

In accordance with the bulk drug provisions in section 127, FDA is preparing to develop a list of bulk drug substances that may be used in compounding that do not have a USP or NF monograph and are not components of approved drugs. To identify candidates for this list, FDA is seeking public input in the form of specific bulk drug nominations. All interested groups and individuals are encouraged to nominate specific bulk drug substances for inclusion on the list. FDA intends for this nomination process to serve as its principal means of identifying list candidates. After evaluating the nominations and, as required by Congress, consulting with the United States Pharmacopeial Convention, Inc., and an advisory committee on compounding (section 503A(d) of the act), FDA will issue the list as a regulation under notice-and-comment rulemaking procedures.

Nominations should include the following information about the bulk drug substance being nominated and the product(s) that will be compounded using such substance. If the information requested is unknown or unavailable, that fact should be noted accordingly.

Bulk Drug Substance

- Ingredient name;
- Chemical name;
- Common name(s);
- Chemical grade or description of the strength, quality, and purity of the ingredient;
- Information about how the ingredient is supplied (e.g., powder, liquid);
- Information about recognition of the substance in foreign pharmacopeias and the status of its registration(s) in other countries, including whether information has been submitted to USP for consideration of monograph development; and
- A bibliography of available safety and efficacy data[2], including any

[1] The term ''bulk drug substance'' is defined in FDA's regulations at 21 CFR 207.3(a)(4) and incorporated in section 127 of FDAMA to mean ''any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or finished dosage form of the drug, but the term does not include intermediates used in the synthesis of such substances.''

[2] FDA recognizes that the available safety and efficacy data is unlikely to be of the same type, amount, or quality as would be required to support a new drug application, but this fact will not preclude a bulk drug substance from consideration for inclusion on the list.