to act as the Federal Coordinating Officer for this declared disaster.

I do hereby determine the following areas of the Commonwealth of Virginia to have been affected adversely by this declared major disaster:

The independent cities of Chesapeake, Norfolk, Portsmouth, Suffolk, and Virginia Beach for Individual Assistance.

All counties within the Commonwealth of Virginia are eligible to apply for assistance under the Hazard Mitigation Grant Program.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 83.537, Community Disaster Loans; 83.538, Cora Brown Fund Program; 83.539, Crisis Counseling; 83.540, Disaster Legal Services Program; 83.541, Disaster Unemployment Assistance (DUA); 83.542, Fire Suppression Assistance; 83.543, Individual and Family Grant (IFG) Program; 83.544, Public Assistance Grants; 83.545, Disaster Housing Program; 83.548, Hazard Mitigation Grant Program)

James L. Witt,

Director.

[FR Doc. 98–25186 Filed 9–18–98; 8:45 am]

BILLING CODE 6718–02–P

FEDERAL HOUSING FINANCE BOARD

Sunshine Act Meeting; Announcing an Open Meeting of the Board

TIME AND DATE: 10:00 A.M., Wednesday, September 23, 1998.

PLACE: Board Room, Second Floor, Federal Housing Finance Board, 1777 F Street, N.W., Washington, D.C. 20006.

STATUS: The entire meeting will be open to the public.

MATTERS TO BE CONSIDERED DURING PORTIONS OPEN TO THE PUBLIC:

- Mortgage Partnership Finance Program: Terms and Conditions.
- Office of Finance—Board Appointments.

CONTACT PERSON FOR MORE INFORMATION: Elaine L. Baker, Secretary to the Board, (202) 408–2837.

William W. Ginsberg,

Managing Director.

[FR Doc. 98–25246 Filed 9–17–98; 10:45 am]

BILLING CODE 6725–01–P

FEDERAL MARITIME COMMISSION

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Federal Maritime Commission.

TIME AND DATE: 10:00 A.M.—September 21, 1998.

PLACE: 800 North Capitol Street, N.W.—Room 904, Washington, D.C.

STATUS: Closed.

MATTER(S) TO BE CONSIDERED: 1. Carrier Pricing Practices in the Transpacific Trades.

CONTACT PERSON FOR MORE INFORMATION: Joseph C. Polking, Secretary, (202) 523–5725.

Joseph C. Polking,

Secretary.

[FR Doc. 98–25316 Filed 9–17–98; 2:55 pm]

BILLING CODE 6730–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0304]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Application for FDA Approval to Market a New Drug

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by October 21, 1998.

ADDRESSES: Submit written comments on the collection of information to Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Application for FDA Approval to Market a New Drug—21 CFR Part 314—(OMB Control Number 0910–0001—Reinstatement)

Under section 505(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(a)), a new drug may not be commercially marketed in the United States, imported, or exported from the United States, unless an approval of an application filed with FDA under section 505(b) or (j) of the act is effective with respect to such drug. Section 505(b) and (j) of the act requires a sponsor to submit to FDA a new drug application (NDA) containing, among other things, full reports of investigations that show whether or not the drug is safe and effective for use, a full list of articles used as components in the drug, a full description of manufacturing methods, samples of the drugs required, specimens of the labeling proposed to be used, and certain patent information as applicable. Under the act, it is the sponsor's responsibility to provide the information needed by FDA to make a scientific and technical determination that the product is safe and effective.

This information collection approval request is for all information requirements imposed on sponsors by the regulations under part 314 (21 CFR part 314), who apply for approval of a NDA in order to market or to continue to market a drug.

The following sections in part 314 set forth the specific format and content requirements for NDA's.

Section 314.50(a) requires that an application form (Form FDA 356h) includes basic introductory information about the drug as well as a checklist of enclosures. (Section 314.50(a) is already approved by OMB under 0910–0338 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.50(b) requires that an index be submitted with the archival copy of the application and that it reference certain sections of the application.

Section 314.50(c) requires that a summary of the application be submitted that presents a good general synopsis of all the technical sections and other information in the application.

Section 314.50(d) requires that the NDA contain the following technical sections about the new drug: Chemistry, manufacturing, and controls; nonclinical pharmacology and toxicology; human pharmacokinetics and bioavailability; microbiology; clinical data; and statistical section.

Section 314.50(e) requires the applicant to submit samples of the drug if requested by FDA. In addition, the archival copy of the application must include copies of the label and all labeling for the drug.

Section 314.50(f) requires that case report forms and tabulations be submitted with the archival copy.