

SUPPLEMENTARY INFORMATION: Released: September 2, 1998.

The next meeting of the North American Numbering Council (NANC) will be held on Tuesday, September 22, from 8:30 a.m., until 5:00 p.m., and on Wednesday, September 23, 1998, from 8:30 a.m., until 5:00 p.m. The meeting will be held at the Federal Communications Commission, 1919 M Street, N.W., Room 856, Washington, D.C., on September 22. The September 23, meeting will be held at the Sheraton City Centre Hotel, 1143 New Hampshire Avenue, N.W., Washington, D.C.

This meeting will be open to members of the general public. The FCC will attempt to accommodate as many people as possible. Admittance, however will be limited to the seating available. The public may submit written statements to the NANC, which must be received two business days before the meeting. In addition, oral statements at the meeting by parties or entities not represented on the NANC will be permitted to the extent time permits. Such statements will be limited to five minutes in length by any one party or entity, and requests to make an oral statement must be received two business days before each meeting. Requests to make an oral statement or provide written comments to the NANC should be sent to Linda Simms at the address under **FOR FURTHER INFORMATION CONTACT**, stated above.

Proposed Agenda

The proposed agenda for the September 22-23, 1998, meeting is as follows:

1. Approval of meeting minutes.
 2. Numbering Resource Optimization (NRO) Working Group Report. Review final recommendation regarding implementation of number pooling by December 1999, and other conservation measures, pursuant to Chief, Common Carrier Bureau letter of March 23, 1998.
- Wednesday, September 23, 1998

3. Continuation of NRO discussion including Industry Numbering Committee Report on 1000 Block Administration Guidelines and Cost Recovery Report concerning 1000 Block Cost Recovery.
4. Local Number Portability Administration (LNPA) Working Group Report.
5. N11 Ad Hoc Working Group Report. Review final report and recommendation, pursuant to the First Report and Order and Further Notice of Proposed Rulemaking. In the Matter of Use of N11 Codes and Other Abbreviated Dialing Arrangements, CC Docket 92-105, FCC 97-51.

6. COCUS and Proposed Line Number Utilization Survey. Review of integrated recommendation from four contributions on question of a rule or clarification of existing rule for reporting utilization data; possible enforcement mechanism; audits; forecasts from resellers; appeals and confidentiality issues.

7. Definition of Reserved Telephone Numbers. Discussion of contributions.
8. Steering Group Report.
9. Other Business.

Federal Communications Commission.

Geraldine A. Matisse,

Chief, Network Services Division, Common Carrier Bureau.

[FR Doc. 98-24026 Filed 9-3-98; 8:45 am]

BILLING CODE 6712-01-M

FEDERAL DEPOSIT INSURANCE CORPORATION**Sunshine Act Meeting**

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that at 2:02 p.m. on Tuesday, September 1, 1998, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session to consider matters relating to the Corporation's resolution activities.

In calling the meeting, the Board determined, on motion of Vice Chairman Andrew C. Hove, Jr., seconded by Director Ellen S. Seidman (Director, Office of Thrift Supervision), concurred in by Ms. Leann Britton, acting in the place and stead of Director Julie L. Williams (Acting Comptroller of the Currency), Director Joseph H. Neely (Appointive), and Chairman Donna Tanoue, that Corporation business required its consideration of the matters on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(8), (c)(9)(A)(ii), and (c)(9)(B) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(8), (c)(9)(A)(ii), and (c)(9)(B)).

The meeting was held in the Board Room of the FDIC Building located at 550-17th Street, NW., Washington, D.C.

Dated: September 2, 1998.

Federal Deposit Insurance Corporation.

James D. LaPierre,

Deputy Executive Secretary.

[FR Doc. 98-24006 Filed 9-2-98; 10:48 am]

BILLING CODE 6714-01-M

FEDERAL RESERVE SYSTEM**Sunshine Act Meeting**

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

TIME AND DATE: 10:00 a.m., Wednesday, September 9, 1998.

PLACE: Marriner S. Eccles Federal Reserve Board Building, 20th and C Streets, N.W., Washington, D.C. 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 matters carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Lynn S. Fox, 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 Web 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: September 2, 1998.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 98-24020 Filed 9-2-98; 11:48 am]

BILLING CODE 6210-01-P

FEDERAL RETIREMENT THRIFT INVESTMENT BOARD**Sunshine Act Meeting**

TIME AND DATE: 9:00 A.M. September 14, 1998.

PLACE: National Finance Center, TANO Building, Conference Room 7, 13800 Old Gentilly Road, New Orleans, Louisiana.

STATUS: Open.

MATTERS TO BE CONSIDERED:

1. Approval of the minutes of the August 10, 1998, Board member meeting.
2. Thrift Savings Plan activity report by the Executive Director.
3. Review of FY 1998 budget and projected expenditures, approval of FY 1999 proposed budget, and review of FY 2000 estimates.
4. Review of KPMG Peat Marwick audit reports:

(a) "Pension and Welfare Benefits Administration Review of Access Controls and Security Over the United States Department of Agriculture, National Finance Center."

(b) "Pension and Welfare Benefits Administration Review of the Thrift Savings Plan Account Maintenance Subsystem, Forfeiture and Forfeiture Restoration Operations and Interfund Transfer Process at the United States Department of Agriculture, National Finance Center."

(c) "Pension and Welfare Benefits Administration Review Backup, Recovery, and Contingency Planning of the Thrift Savings Plan at the United States Department of Agriculture, National Finance Center."

(d) "Pension and Welfare Benefits Administration Review of the Thrift Savings Plan Billing Process at the United States Department of Agriculture, National Finance Center."

CONTACT PERSON FOR MORE INFORMATION: Tom Trabucco, Director, Office of External Affairs (202) 942-1640.

Dated: September 2, 1998.

Roger W. Mehle,

Executive Director, Federal Retirement Thrift Investment Board.

[FR Doc. 98-24058 Filed 9-2-98; 2:30 pm]

BILLING CODE 6760-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N-0192]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Establishment and Product License Applications: Forms FDA 2599, 2599a, 2600, 2600b, 3066, 3086, 3096, 3098, 3098a, 3098b, 3098c, 3098d, 3098e, 3210, 3213, 3214, and 3314

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 5, 1998.

ADDRESSES: Submit written comments on the collection of information to the

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: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

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.

Establishment and Product License Applications: Forms FDA 2599, 2599a, 2600, 2600b, 3066, 3086, 3096, 3098, 3098a, 3098b, 3098c, 3098d, 3098e, 3210, 3213, 3214, and 3314—21 CFR 601.2 and 601.12—(OMB Control Number 0910-0124—Extension)

FDA is the Federal agency charged with responsibility for determining that drugs and biological products are safe and effective. Manufacturers of biological products for human use must file an application for FDA approval of the product prior to introducing it into interstate commerce. The information provided by manufacturers on these license application forms is necessary for FDA to carry out its mission of protecting the public health and helping to ensure that biologics for human use have been shown to be safe and effective. The uniform format of the forms provides for orderly, efficient review by the Center for Biologics Evaluation and Research (CBER) staff and expedites the licensing process as well as documenting for future reference the methods and procedures that have been approved for use at each manufacturing location. Statutory authority for the collection of this information is provided by section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262).

Section 601.2 (21 CFR 601.2) requires that manufacturers of biological products regulated under the PHS Act submit an establishment license application (ELA) and a product license application (PLA), or a biologic license application (BLA) to CBER for review and approval prior to marketing a biological product in interstate commerce. Blood and blood components fall within the category of biological products. All establishments collecting and/or preparing blood and blood components for sale or distribution in interstate commerce are subject to the licensing application

provisions of section 351 of the PHS Act. Section 601.12 (21 CFR 601.12) requires manufacturers of a biologic for human use to file supplemental applications for all important changes to applications previously approved prior to implementing such changes. In addition to §§ 601.2 and 601.12, other regulations provide additional standards for human blood and blood products, which require submission of certain information in a license application, including 21 CFR 640.17, 640.21(c), 640.25(c), 640.56(c), 640.64(c), 640.74(a) and (b)(2), and 680.1(b)(2)(iii) and (c). The information collection requirements in the preceding regulations and their associated reporting burdens are provided under the burden estimated for §§ 601.2 and 601.12 and the application form in approved OMB control number 0910-0338.

As outlined in the President's November 1995 National Performance Review's document entitled "Reinventing the Regulation of Drugs Made From Biotechnology," FDA intends to use a single harmonized application form for all drug and licensed biological products. FDA revised Form FDA 356h, "Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use," for this purpose and announced its availability in the **Federal Register** of July 8, 1997 (62 FR 36558). This notice described FDA's intent to phase in the use of the new Form FDA 356h for all biological products and stated that applicants submitting new drug applications (NDA's), abbreviated new drug applications (ANDA's), abbreviated antibiotic drug applications (AADA's), and BLA's for biologic products specified in § 601.2(c) could begin to use the new Form FDA 356h immediately. The notice also advised such applicants that they will be required to use revised Form FDA 356h beginning January 8, 1998. In the interim period, the old Form FDA 356h and the new Form FDA 356h were to be acceptable alternatives for NDA's, ANDA's, AADA's, and BLA's.

In future **Federal Register** notices, FDA will advise applicants for the products not yet using the new Form FDA 356h, when they may voluntarily begin, and when they will be required to use the new Form FDA 356h. FDA is in the process of preparing guidance documents on the content and format of the chemistry, manufacturing, and controls section, and establishment description section of the new Form FDA 356h for those biological products not yet using the new form. As these guidance documents are completed, FDA will begin accepting the new Form