

1. *Concord EFS, Inc.*, Memphis, Tennessee; to acquire Logix Companies, LLC, Longmont, Colorado, and thereby engage in data processing activities, pursuant to § 225.28(b)(14) of Regulation Y.

Board of Governors of the Federal Reserve System, January 9, 2002.

**Robert deV. Frierson,**

*Deputy Secretary of the Board.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

#### Statement of Organization, Functions and Delegations of Authority

Part A, Office of the Secretary, Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (HHS) is being amended at Chapter AA, Immediate Office of the Secretary, as last amended at 44 FR 31045, May 30, 1979. This reorganization is to establish a new Chapter AAB, "Office of Public Health Preparedness (OPHP)" to direct activities of the Department of Health and Human Services relating to protecting the civilian population from acts of bioterrorism and other public health emergencies. The changes are as follows: Under Part A, Office of the Secretary, Chapter AA, make the following changes:

A. Under Section AA.10 "Organization," add the following new component: Office of Public Health Preparedness.

B. Establish a new chapter AAB, "Office of Public Preparedness (OPHP)" to read as follows:

#### Office of Public Health Preparedness

AAB.00 MISSION

AAB.10 ORGANIZATION

AAB.20 FUNCTIONS

*Section AAB.00 Mission.* The Office of Public Health Preparedness (OPHP) shall direct the Department of Health and Human Services' efforts to prepare for, protect against, respond to, and recover from all acts of bioterrorism and other public health emergencies that affect the civilian population; and shall serve as the focal point within HHS for these activities.

*Section AAB.10 Organization:* The Office of Public Health Preparedness (OPHP) is headed by a Director, who reports directly to the Secretary, and serves as the Secretary's principal advisor on HHS activities relating to

protecting the civilian population from acts of bioterrorism and other public health emergencies.

*Section AAB.20 Functions:* The Office of Public Health Preparedness (OPHP) includes the following responsibilities:

1. Serves as the Secretary's principal advisor on matters relating to bioterrorism and public health emergencies.

2. Acts as the Department's liaison with the Office of Homeland Security.

3. Serves as the principal representative of the Department to other Federal agencies and the private sector in all matters related to bioterrorism, and other public health emergencies.

4. Directs HHS Operating and Staff Division implementation of a comprehensive HHS strategy to protect the civilian population from acts of bioterrorism and other public health emergencies. The OPHP will work with the OPDIVS and STAFFDIVs to ensure the adequacy of HHS strategy for preparing, preventing, responding to, and recovering from acts of bioterrorism and other public health emergencies.

Dated: December 14, 2001.

**Tommy G. Thompson,**

*Secretary.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket Nos. 01M-0271, 01M-0255, 01M-0210, 01M-0173, 01M-0254, 01M-0227, 01M-0226, and 01M-0270]

#### Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the agency's Dockets Management Branch.

**ADDRESSES:** Submit written requests for copies of summaries of safety and effectiveness to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket

number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

#### FOR FURTHER INFORMATION CONTACT:

Thinh Nguyen, Center for Devices and Radiological Health (HFZ-402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2186.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule to revise §§ 814.44(d) and 814.45(d) (21 CFR 814.44(d) and 814.45(d)) to discontinue publication of individual PMA approvals and denials in the **Federal Register**. Instead, revised §§ 814.44(d) and 814.45(d) state that FDA will notify the public of PMA approvals and denials by posting them on FDA's home page on the Internet at <http://www.fda.gov>, by placing the summaries of safety and effectiveness on the Internet and in FDA's Dockets Management Branch, and by publishing in the **Federal Register** after each quarter a list of available safety and effectiveness summaries of approved PMAs and denials announced in that quarter.

FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The following is a list of approved PMAs for which summaries of safety