issued stock with special voting rights to any particular group or class.[33] In this regard, we understand that, in connection with certain foreign utility privatization transactions, foreign governments hold special or ''golden'' shares that give them veto rights with respect to certain corporate transactions. We recognize that these shares are intended to protect the foreign government's regulatory interests rather than to create the type of abusive capital structure that led to passage of the Act. Are these types of arrangements inconsistent with the Act?

We would also consider whether foreign law imposed any impediments on our ability to inspect the foreign holding company and its subsidiaries. Such impediments could be detrimental to the public interest, the interests of investors and consumers, and ''the proper functioning of [a] holding-company system.''

4. Substantive Regulation of Foreign Holding Companies

The Holding Company Act imposes a comprehensive federal framework of regulation on registered holding companies. A registered foreign holding company would be subject to this framework to the same degree as a registered domestic company. For example, we must approve:

- issuances and sales of securities; [34]
- certain acquisitions; [35] and
- sales of utility assets.

We also have jurisdiction over intrasystem transactions. For example, section 12 requires our prior approval for a registered holding company or its subsidiary ''to lend or in any manner extend its credit to or indemnify any company in the same holding-company system.'' Section 13 authorizes us to regulate service, sales and construction contracts between operating utilities within a registered system and other companies within the same system and require that such services be performed at cost. Finally, registered holding companies are subject to extensive reporting, recordkeeping and accounting requirements.

Despite our jurisdiction over registered holding companies, the EWGs and FUCOs owned by a foreign registered holding company, like those of a domestic registered holding company, would generally be exempt from the Act. Moreover, a FUCO may issue and acquire securities without our authorization. A registered holding company with large FUCO operations may be able to issue securities through a FUCO to finance other businesses. Does this raise significant policy issues under the Act, even if the holding company's U.S. utilities do not have any liability with respect to those financings?

5. Accounts and Records; Jurisdiction

The Holding Company Act contains a number of provisions designed to prevent companies in registered holding company systems from engaging in abusive affiliate transactions. In order for these provisions to be effective, we were given the authority to monitor intra-system transactions by requiring the making and keeping of holding company system records and mandating that we have access to those records.[36]

We anticipate that we would be able to exercise this authority with respect to foreign registered holding companies. We request any information concerning possible impediments to our exercise of our inspection authority and jurisdiction. Are there difficulties in obtaining information from foreign companies that are inconsistent with regulation under the Holding Company Act? What types of safeguards or limitations on ownership might prevent or minimize such risks?

6. Other Issues

Are there any other policy issues related to foreign acquisitions of U.S. utilities that we should consider? For example, do we need to consider national security interests that would be implicated by a foreign acquisition of a U.S. utility? [37] We note that the President may investigate the national security effects of ''foreign control of persons engaged in interstate commerce in the United States,'' and suspend or prohibit any acquisition, merger, or takeover of such persons in order to protect the national security.[38] United States companies have acquired significant interests in FUCOs over the past several years. Would restrictions on foreign ownership of U.S. utilities be likely to lead to restrictions on investment in FUCOs by U.S. investors?

Dated: December 14, 1999.

By the Commission.

Margaret H. McFarland,

Deputy Secretary.

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[33] *See* section 11(b)(2).

[34] Sections 6 and 7 require our prior approval under specified qualitative standards for most types of securities issuances.

[35] Section 11(b)(1) confines the nonutility businesses of a registered holding company to those that have a functional relationship to its core utility business. Rule 58 under the Act permits a registered holding company to acquire certain types of non-utility businesses without our approval.

[36] *See* section 15 of the Act.

[37] In response to our prior request for comments, APS raised national security concerns. Most of the other commenters did not believe that there were any national security concerns or that any such concerns should be addressed by Congress. Some federal laws specifically restrict foreign ownership of certain regulated entities, while others provide for ownership subject to certain conditions. *See, e.g.*, 42 U.S.C. 2131–2134 (prohibition of foreign ownership or control of facilities that produce or use nuclear materials). The Nuclear Regulatory Commission (''NRC'') has developed a ''Standard Review Plan'' for use in reviewing nuclear power plant licenses involving foreign interests. *See* Final Standard Review Plan on Foreign Ownership, Control, or Domination, 64 FR 5355 (Sept. 28, 1999). The NRC has approved, with certain restrictions on foreign ownership and control, transfers of the operating license for three nuclear power plants. *See NRC Approves AmerGen's Takeover of Clinton Plant*, The Energy Daily, Nov. 30, 1999 (describing transfers of two operating licenses to AmerGen Energy Co., a company jointly owned by PECO Energy Co., an inactive registered holding company, and British Energy Inc., a British utility company), and PacifiCorp (Trojan Nuclear Plant), 64 FR 63060 (Nov. 18, 1999) (NRC order approving transfer of licenses to ScottishPower). *See also supra* note 5.

[38] 50 U.S.C. App. 2170. The President has established the Committee on Foreign Investment in the United States to administer this authority. *See* 31 CFR 800.101, *et seq.*

DEPARTMENT OF LABOR

Employment and Training Administration

20 CFR Part 604

RIn 1205–AB21

Birth and Adoption Unemployment Compensation; Correction

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice of Proposed Rulemaking; Correction.

SUMMARY: This document corrects the preamble to a notice of proposed rulemaking published in the **Federal Register** of December 3, 1999 (64 FR 67971), concerning Birth and Adoption Unemployment Compensation. The preamble to the notice of proposed rulemaking provided only a mailing address to which written comments could be submitted. This correction provides an e-mail address to which comments may be submitted.

FOR FURTHER INFORMATION CONTACT: Gerard Hildebrand, Unemployment Insurance Service, ETA, U.S. Department of Labor, 200 Constitution Avenue, NW, Room S–4231, Washington, DC 20210. Telephone: (202) 219–5200 ext. 391 (this is not a toll-free number); facsimile: (202) 219–8506.

Correction

In the notice of proposed rulemaking FR Doc. 99–30445, beginning on page 67971 in the issue of December 3, 1999, make the following correction in the Addresses section. On page 67972 in the first column, add at end of the first sentence (after the ZIP code) the following: '', or by e-mail to the following address: commentonbaauc@doleta.gov.''

Dated: December 15, 1999.

Raymond L. Bramucci,

Assistant Secretary of Labor.

[FR Doc. 99–32987 Filed 12–20–99 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 807

[Docket No. 99N–4784]

Premarket Notification; Requirement for Redacted Version of Substantially-Equivalent Premarket Notification

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its premarket notification regulations to require applicants to submit a redacted version of each premarket notification submission for which FDA has issued an order declaring a device to be substantially equivalent to a legally marketed predicate device. The purpose of this requirement is to provide applicants improved opportunity to protect nonpublic information contained in their premarket notifications while facilitating the release of information to which the public is entitled under the Federal Food, Drug, and Cosmetic Act (the act); the Freedom of Information Act; and FDA's Public Information regulations. The proposed rule does not require submission of a redacted version of any premarket notification received by FDA prior to the effective date of the regulation.

DATES: Submit written comments by March 22, 2000. Submit written comments on the information collection requirements by January 20, 2000.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written comments on information collection requirements to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Bldg., 725 17th St. NW., Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Regulations Staff (HFZ–215), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20857, 301–827–2974.

SUPPLEMENTARY INFORMATION:

I. Background

Under the act, 21 U.S.C. 301 *et seq.*, FDA clears medical devices for commercial distribution in the United States through three regulatory processes: Premarket approval (PMA), product development protocol (PDP), and premarket notification (a premarket notification is generally referred to as a ''510(k)'' after the section of the act where the requirement is found). In addition, a significant number of devices have been exempted, subject to the limitations on exemptions, from any requirement to obtain premarket notification clearance because FDA has determined that the remaining general controls and special controls are adequate to provide a reasonable assurance of the safety and effectiveness of those devices. A variety of general controls, such as good manufacturing practices (GMP's), establishment registration and device listing, and Medical Device Reporting (problem reporting), and special controls for class II devices, are applicable to devices exempted from premarket notification to control the risks presented by these devices. For additional information on exemption from premarket notification, see 21 CFR 807.85 and FDA's medical device classification regulations, 21 CFR parts 862 through 892.

A. Premarket Notification

Of the three regulatory processes used by FDA to clear medical devices for commercial distribution, the premarket notification or 510(k) process is the most commonly used. The following table 1 summarizes FDA's experience during fiscal year (FY) 1998:

TABLE 1.—PRODUCT APPLICATIONS PROCESSED DURING FY 1998

Responsible center	Premarket Notifications		Premarket Approval Applications		Product Development Protocols		
	Received	Clear	Received	Approved	Received	Approved[1]	Complete
CBER	33	44	2	0	0	0	0
CDRH	4,623	3,824	55	46	11	4	0
All FDA	4,656	3,868	57	46	11	4	0

[1] Approval of a PDP protocol does not constitute marketing approval. A Notice of Completion must be submitted and approved before a device may be marketed under a PDP.

The purpose of a premarket notification is to demonstrate that the new device is substantially equivalent to a legally-marketed predicate device. A predicate device can be any of the following: A device legally marketed prior to May 28, 1976 (the date the Medical Device Amendments of 1976 and its premarket notification requirement became law); a device which has been reclassified from class III into class I or class II (the act provides three classes of devices: Class I devices are regulated primarily through general controls, such as registration, listing, and GMP's; class II devices are subject to both general controls and special controls, such as performance standards; class III devices are subject to general and special controls and must also undergo premarket review and approval); or a device which has been found to be substantially equivalent through the 510(k) premarket notification process.

Under section 513(i) of the act (21 U.S.C. 360c), a device is substantially equivalent if it has the same intended use and technological characteristics as a predicate device, or has different characteristics but data demonstrate that the new device is as safe and effective as the predicate device and does not