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FEDERAL RESERVE SYSTEM

12 CFR Part 272

[Docket No. R–1142]

Federal Open Market Committee; Amendment to Rules of Procedure

AGENCY: Federal Open Market Committee.

ACTION: Final rule.

SUMMARY: The Federal Open Market Committee has amended its definition of a quorum of the Committee. The amendment is designed to enhance the Committee's ability to perform its functions in the event of a national emergency.

DATES: The rule is effective February 6, 2003.

FOR FURTHER INFORMATION CONTACT: Kieran J. Fallon, Senior Counsel (202–452–5270), Legal Division; Board of Governors of the Federal Reserve System; or Normand R.V. Bernard, Deputy Secretary (202–452–3606), Federal Open Market Committee, 20th Street and Constitution Avenue, NW., Washington, DC 20551. Users of Telecommunication Device for Deaf (TTD) only, call (202) 263–4869.

SUPPLEMENTARY INFORMATION: The Federal Open Market Committee (Committee) is composed of (1) all of the members of Board of Governors of the Federal Reserve System (Board), and (2) five representatives of the Federal Reserve Banks elected in the manner provided in the Federal Reserve Act (Act).[1] Because the Board has an authorized membership of seven Governors, the Committee has a maximum authorized strength of 12 members (7 Board members and 5 Federal Reserve Bank representatives).

The Act does not define a quorum of the Committee. Since the current structure of the Committee was established in 1936, the Committee itself has defined a quorum of the Committee to be seven members, including alternates serving in place of a primary Federal Reserve Bank representative.[2]

The Committee's current quorum rule would prevent the Committee from taking action, including adjusting the Committee's target for the federal funds rate, if an act of war, terrorist attack or other catastrophic event reduced the membership of the Committee to below seven members (including alternates). In light of this possibility, the Committee has amended its definition of a quorum of the Committee. Under the Committee's amended rule, a quorum of the Committee will continue to be seven members unless there are fewer than seven members of the Committee in office, in which case a quorum of the Committee will consist of the number of members in office. As under the current rule, alternates serving in place of an absent primary Federal Reserve Bank representative are considered members for purposes of determining whether a quorum of the Committee is available.

The Committee believes that the revised quorum rule will enhance the Committee's ability to fulfill its critical monetary policy responsibilities in a national emergency. At the same time, the revised rule should not alter the functioning of the Committee in normal operating environments. As noted above, under the revised rule, a quorum of the Committee would continue to be seven members whenever seven or more members of the Committee are in office. The Committee notes that the Securities and Exchange Commission (SEC) has revised its quorum rule in a similar fashion to ensure that the SEC could continue to function if the 5-member SEC ever had fewer than 3 commissioners in office.[3]

The amended rule relates solely to the internal procedure of the Committee. Accordingly, the public notice, public comment and delayed effective date provisions of the Administrative Procedure Act do not apply. *See* 5 U.S.C. 553(b) and (d). Because public notice and comment is not required, the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) also does not apply to the amended rule.

List of Subjects

Administrative practice and procedure, Federal Open Market Committee, Organization and functions (Government agencies).

For the reasons set out in the preamble, the Federal Open Market Committee amends 12 CFR part 272 as follows:

PART 272—FEDERAL OPEN MARKET COMMITTEE—RULES OF PROCEDURE

1. The authority citation for part 272 continues to read as follows:

Authority: 5 U.S.C. 552.

2. Section 272.3(c) is revised to read as follows:

§ 272.3 Meetings

* * * * *

(c) *Quorum.* Seven members constitute a quorum of the Committee for purposes of transacting business except that, if there are fewer than seven members in office, then the number of members in office constitute a quorum. For purposes of this paragraph (c), members of the Committee include alternates acting in the absence of members. Less than a quorum may adjourn a meeting of the Committee from time to time until a quorum is in attendance.

* * * * *

[1] *See* 12 U.S.C. 263(a). Pursuant to the Act, the Federal Reserve Banks also elect an alternate for each primary Federal Reserve Bank representative on the Committee. Each alternate is authorized to serve on the Committee in the absence of the relevant primary representative. Each primary and alternate Federal Reserve Bank representative on the Committee must be a President or First Vice President of a Federal Reserve Bank. *Id.*

[2] *See* 12 CFR 272.3(c). From 1936 to 1973, the Committee's quorum rule was reflected in the Committee's By-Laws. *See* Minutes of the Committee's Meeting of March 18, 1936. In 1973, the Committee's By-Laws were rescinded and the Committee's quorum rule was incorporated into the Committee's Rules of Procedure. *See* 38 FR 2754, Jan. 30, 1973.

[3] *See* 17 CFR 200.41; 60 FR 17201, Apr. 5, 1995. The enabling statutes of the SEC, like those of the Committee, do not define a quorum of the SEC. The SEC's revised quorum rule has been upheld by two separate Federal courts. *See Falcon Trading Group, Ltd.* v. *SEC,* 102 F.3d 579 (D.C. Cir. 1996); *SEC* v. *Feminella,* 947 F. Supp. 722 (S.D.N.Y. 1996).

By order of the Federal Open Market Committee, January 30, 2003.

Vincent R. Reinhart,

Secretary, Federal Open Market Committee.

[FR Doc. 03–2582 Filed 2–5–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 201

[Docket No. 00N–1463]

RIN 0910–AB78

Labeling Requirements for Systemic Antibacterial Drug Products Intended for Human Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to require that the labeling for all systemic antibacterial drug products (i.e., antibiotics and their synthetic counterparts) intended for human use include certain statements about using antibiotics in a way that will reduce the development of drug-resistant bacterial strains. The final rule reflects a growing concern in FDA and the medical community that unnecessary use of systemic antibacterials has contributed to a dramatic increase in recent years in the prevalence of drug-resistant bacterial infections. The final rule is intended to encourage physicians to prescribe systemic antibacterial drugs only when clinically necessary. The final rule is also intended to encourage physicians to counsel their patients about the proper use of such drugs and the importance of taking them exactly as directed.

DATES: This rule is effective February 6, 2004.

FOR FURTHER INFORMATION CONTACT: Christine F. Rogers, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

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I. Background

In the **Federal Register** of September 19, 2000 (65 FR 56511), FDA proposed to amend its regulations to require that the labeling for all systemic antibacterial drug products (i.e., antibiotics and their synthetic counterparts) intended for human use include certain statements about using antibiotics in a way that will reduce the development of drug-resistant bacterial strains. The new labeling is intended to help educate physicians and the public about the resistance problem and to encourage physicians to prescribe systemic antibacterial drugs only when clinically necessary. FDA personnel involved in drafting the statements included practicing physicians who are in a position to evaluate the effect of the labeling on physicians. The statements were also reviewed by other practicing physicians in the agency.

Antibacterial resistance among disease-causing bacteria represents a serious and growing public health problem in the United States and worldwide. Many bacterial species, including the species that cause pneumonia and other respiratory tract infections, meningitis, and sexually transmitted diseases, are becoming increasingly resistant to the antibacterial drugs used to treat them. Several bacterial species have developed strains that are resistant to every approved antibiotic, thus severely limiting the therapeutic options available for adequate treatment. The incidence of resistance in both hospital- and community-acquired infections has increased dramatically in the past several years, making many common illnesses more difficult to treat than they were only 5 or 10 years ago.

According to the Centers for Disease Control and Prevention (CDC), half of the 100 million antibiotic prescriptions a year written by office-based physicians in the United States are unnecessary because they are prescribed for the common cold and other viral infections, against which antibiotics are not effective (Ref. 1). Unnecessary use of antibiotics in hospitals is common as well. The more an antibiotic is used, the more likely it is that bacteria will develop resistance to it. Thus, using antibiotics when they are not necessary contributes to the increasing prevalence of antibacterial resistance without providing any patient benefit.

Educating physicians and the public about the resistance problem and discouraging unnecessary use of antibiotics are important steps to decrease the prevalence of antibacterial resistance and slow its future development and spread. FDA believes that professional labeling has an important role in that educational effort. Therefore, FDA is requiring that the labeling for systemic antibacterial drug products include certain statements about unnecessary use of antibiotics and the link between such use and the emergence of drug-resistant bacterial strains.

Recent reports of a reduction in antibiotic prescribing raise the hope that the trend in overuse of antibiotics can be reversed and provide additional support for the need to include information in labeling to ensure the continued safety and efficacy of antibiotics (Refs. 2 and 3). The studies reported were conducted in children seen in outpatient practice and have not been confirmed in either adults or hospitalized patients. Nevertheless, as the authors of the two studies and the editorial (Ref. 4) that accompanied them note, efforts to promote the appropriate use of antibiotics have likely contributed to a decrease in antibiotic prescribing. These authors observe that it is important to continue such efforts if these gains are to be maintained. The authors cite the ongoing role of the U.S. Public Health Service Action Plan (Ref. 5) to combat antimicrobial resistance. FDA is one of the three lead agencies for this plan. The plan indicates that educational efforts should be one of the highest priorities and placing information on the labeling of systemic antimicrobial products is specifically cited in the plan.

II. Highlights of the Final Rule

The final rule amends FDA regulations to require that all systemic antibacterial drug products (i.e., antibiotics and their synthetic counterparts) intended for human use contain additional labeling information