scheduled for the meeting; or you may contact the Board's Web site at *http://www.federalreserve.gov* for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Board of Governors of the Federal Reserve System, September 5, 2008.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E8–20989 Filed 9–5–08; 4:15 pm]

BILLING CODE 6210–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2006–P–0081 (formerly Docket No. 2006P–0178) and FDA–2005–P–0369 (formerly Docket No. 2005P–0023)]

Determination That TEQUIN (Gatifloxacin) Was Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that TEQUIN (gatifloxacin) Tablets, Injection, and Oral Suspension, were withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not accept or approve abbreviated new drug applications (ANDAs) for gatifloxacin oral tablets, injection, or oral suspension that refer to any previously approved dosage forms and strengths of TEQUIN (gatifloxacin).

FOR FURTHER INFORMATION CONTACT: Elena Cohen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6228, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved under a new drug application (NDA). ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Drugs are removed from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (section 505(j)(7)(C) of the act; § 314.162 (21 CFR 314.162)).

FDA will not approve an ANDA if the listed drug has been withdrawn from sale for safety or effectiveness reasons (section 505(j)(4)(I) of the act). Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. A drug that has been withdrawn from the market for safety or effectiveness reasons is not a listed drug (21 CFR 314.3(b)). FDA may not approve an ANDA that does not refer to a listed drug. FDA currently has pending one or more ANDAs that refer to TEQUIN (gatifloxacin).

Bristol-Myers Squibb Co. (BMS) is the holder of three NDAs[1] for TEQUIN tablets, injection, and oral suspension as listed in the following table:

TABLE 1.—APPROVED TEQUIN PRODUCTS

NDA No.	Active Ingredients	Strength	Dosage Form/Route
21–061	Gatifloxacin	200 milligrams (mg)	Tablet; oral
21–061	Gatifloxacin	400 mg	Tablet; oral
21–062	Gatifloxacin	Equivalent to 10 mg/milliliter (mL) (200 mg)	Injectable; injection
21–062	Gatifloxacin	400 mg/40 mL (10 mg/mL)	Injectable; injection
21–062	Gatifloxacin in dextrose 5% in plastic container	200 mg/100 mL (2 mg/mL)	Injectable; injection
21–062	Gatifloxacin in dextrose 5% in plastic container	400 mg/200mL (2 mg/mL)	Injectable; injection
21–678	Gatifloxacin	200 mg/5 mL	Suspension; oral

TEQUIN is an antibacterial drug indicated for the treatment of infections due to susceptible strains of designated microorganisms in the following conditions: Acute bacterial exacerbation of chronic bronchitis; acute sinusitis;

[1] On December 17, 1999, FDA approved NDAs 21–061 and 21–062 for community-acquired pneumonia, acute bacterial exacerbation of chronic bronchitis, acute bacterial sinusitis, uncomplicated urinary tract infections, complicated urinary tract infections, pyelonephritis, and uncomplicated gonorrhea. The December 17, 1999, approval letter also stated that indications for uncomplicated skin and skin structure infections were approvable pending the submission of certain postmarketing data. For administrative purposes, the agency assigned administrative NDAs 21–404 (TEQUIN Tablets) and 21–405 (TEQUIN Injections) for the treatment of uncomplicated skin and skin structure infections. BMS provided a complete response, and upon approval on October 17, 2002, NDAs 21–404 and 21–405 were retired by FDA. The approvals and all other submissions for the treatment of uncomplicated skin and skin structure infections were incorporated in the original NDAs, 21–061 and 21–062. NDAs 21–404 and 21–405 are not listed in the Orange Book, but can be found through a search at *Drugs@FDA*.

community-acquired pneumonia; uncomplicated skin and skin structure infections; uncomplicated and complicated urinary tract infections; pyelonephritis; uncomplicated urethral and cervical gonorrhea; and acute, uncomplicated rectal infections in women.

In January 2003, FDA received revised product labeling relating to several approved supplements for TEQUIN (gatifloxacin). This revised labeling deleted references to TEQUIN injection, 10 milligrams/milliliter (mg/mL) (200 mg), indicating that this product was no longer being marketed; therefore, the product was moved from the prescription drug product list to the ''Discontinued Drug Product List'' section of the Orange Book. In response to a citizen petition from Apotex Corp. (Docket No. FDA–2005–P–0369),[2] FDA stated, in the **Federal Register** of February 3, 2006 (71 FR 5858), that TEQUIN injection, 10 mg/mL (200 mg), was not withdrawn for reasons of safety and effectiveness.

On May 1, 2006, Public Citizen Research Group submitted a citizen petition (Docket No. FDA–2006–P–0081),[3] under 21 CFR 10.30, requesting that FDA immediately ban TEQUIN because of the increased risk of dysglycemia (hypoglycemia, low blood sugar, and hyperglycemia, high blood sugar) in humans. Public Citizen states that it reached its conclusion based on: (1) The relatively high numbers and rates of gatifloxacin-associated dysglycemia adverse event reports calculated from data collected by FDA's Adverse Event Reporting System (AERS) and Health Canada's Adverse Drug Reaction Monitoring Program; (2) a study by Park-Wyllie et al., published in March 2006 in the New England Journal of Medicine, that showed that patients (diabetic and nondiabetic) receiving gatifloxacin had approximately 17 times the odds of having a hyperglycemic episode and 4 times the odds of having a hypoglycemic episode compared to those taking macrolide antibiotics; and (3) the relatively high numbers and rates of gatifloxacin-associated dysglycemic events in the manufacturer's safety studies in uninfected patients and other studies in infected patients, including clinical trials, cohort studies, case-control studies, postmarketing surveillance studies, and case reports.

In June 2006, BMS announced that it would no longer market TEQUIN. In light of pending ANDAs and the citizen petition, FDA examined whether all TEQUIN products, including TEQUIN (gatifloxacin) injection, 10 mg/mL (200 mg), were withdrawn from the market for reasons of safety or effectiveness. After considering the citizen petition and reviewing agency records concerning the drug product, analyses of AERS reports, and relevant literature, FDA has determined under § 314.161 that TEQUIN was withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will remove all TEQUIN products from the Orange Book (§ 314.162). FDA will not accept or approve ANDAs that refer to these drug products.

Therefore, the agency has determined, under § 314.161, that all dosage forms and strengths of TEQUIN (gatifloxacin) listed in the table of this document were withdrawn from sale for reasons of safety. TEQUIN (gatifloxacin) will be removed from the list of drug products published in the Orange Book. FDA will not accept or approve ANDAs that refer to any dosage form or strength of TEQUIN (gatifloxacin).

Dated: September 2, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–20938 Filed 9–8–08; 8:45 am]

BILLING CODE 4160–01–S

[2] This citizen petition was originally assigned docket number 2005P–0023/CP1. The number was changed to FDA–2005–P–0369 as a result of FDA's transition to its new docketing system (*Regulations.gov*) in January 2008.

[3] This citizen petition was originally assigned docket number 2006P–0178. The number was changed to FDA–2006–P–0081 as a result of FDA's transition to its new docketing system (*Regulations.gov*) in January 2008.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–N–0451] (formerly FDA–2004–N–0226)

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 020

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a publication containing modifications the agency is making to the list of standards FDA recognizes for use in premarket reviews (FDA recognized consensus standards). This publication, entitled ''Modifications to the List of Recognized Standards, Recognition List Number: 020'' (Recognition List Number: 020), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Effective September 9, 2008. Submit written or electronic comments concerning this document at any time.

ADDRESSES: Submit written requests for single copies of ''Modifications to the List of Recognized Standards, Recognition List Number: 020'' to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health (CDRH) (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your requests, or fax your request to 240–276–3151. Submit written comments concerning this document, or recommendations for additional standards for recognition, to the contact person (see **FOR FURTHER INFORMATION CONTACT**). Submit electronic comments to *standards@cdrh.fda.gov*. This document may also be accessed on FDA's Internet site at *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/cdrhnew.cfm*. See section VI of this document for electronic access to the searchable database for the current list of FDA recognized consensus standards, including Recognition List Number: 020 modifications and other standards related information.

FOR FURTHER INFORMATION CONTACT: Carol L. Herman, Center for Devices and Radiological Health (HFZ–84), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 240–276–8714.

SUPPLEMENTARY INFORMATION:

I. Background

Section 204 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105–115) amended section 514 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360d). Amended section 514 allows FDA to recognize consensus standards developed by international and national organizations for use in satisfying portions of device premarket review submissions or other requirements.

In a notice published in the **Federal Register** of February 25, 1998 (63 FR 9561), FDA announced the availability of a guidance entitled ''Recognition and Use of Consensus Standards.'' The document described how FDA would implement its standard recognition program and provided the initial list of recognized standards.

Modifications to the initial list of recognized standards, as published in