DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

[TABLE 1.—APPROVED TEQUIN PRODUCTS]

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

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; 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.

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), 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–2005–P–0081), under 21 CFR 10.30, requesting that 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration


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.


ADDRESSES: Submit written or electronic comments concerning this document at any time.

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


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

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{2} This citizen petition was originally assigned docket number 2005P–0023/C1. 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.