DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration


Determination That TEQUIN (Gatifloxacin) Was Withdrawn From Sale for Reasons of Safety or Effectiveness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and Drug Administration (FDA) has determined that TEQUIN (gatifloxacin) Tablets, Injection, and Oral Suspension, were withdrawn from sale for reasons of safety or effectiveness.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of the drug’s NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness [section 505(j)(7)(C) of the act; §314.162 (21 CFR 314.162)].

FDA will not approve an ANDA if the listed drug has been withdrawn from sale for safety or effectiveness reasons [section 505(j)(4)(I) of the act].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 NDAs1 for TEQUIN tablets, injection, and oral suspension as listed in the following table:

<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>21–062</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 21–045 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), 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), 2 under 21 CFR 10.30, requesting that FDA examine 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.

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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.


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).

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