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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N-0221]

Otsuka Pharmaceutical Co., Ltd.; Withdrawal of Approval of a New Drug Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new drug application (NDA) for RAXAR (grepafloxacin hydrochloride (HCl)) Tablets held by Otsuka Pharmaceutical Co., Ltd. (Otsuka), c/o Otsuka Pharmaceutical Development & Commercialization, Inc., 2440 Research Blvd., Rockville, MD 20850. Otsuka has voluntarily requested that approval of this application be withdrawn because the product is no longer marketed, thereby waiving its opportunity for a hearing.

DATES: Effective [insert date of publication in the FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

Florine P. Purdie,  
Center for Drug Evaluation and Research (HFD-7),  
Food and Drug Administration,  
5600 Fishers Lane,  
Rockville, MD 20857,  
301-594-2041.

SUPPLEMENTARY INFORMATION: In a letter dated March 5, 2003, Otsuka requested that FDA withdraw approval of NDA 20-695 for RAXAR (grepafloxacin HCl) Tablets, stating that

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the product was no longer being marketed. In FDA's acknowledgment letter of June 20, 2003, the agency informed Otsuka that RAXAR (grepafloxacin HCl) Tablets, indicated for the treatment of a variety of infections, had been removed from the market because of safety concerns; in its follow-up letter of January 12, 2007, the agency also informed Otsuka that it had determined that the RAXAR NDA should be withdrawn under § 314.150(d) (21 CFR 314.150(d)) because of its effect on cardiac repolarization, manifested as QTc interval prolongation on the electrocardiogram, which could put patients at risk of Torsade de Pointes. In its letter of March 20, 2007, Otsuka concurred in the agency's determination to initiate withdrawal of the RAXAR NDA and waived its opportunity for a hearing, provided under 21 CFR 214.150(a) and (b).

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(e)), § 314.150(d), and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.105(a)), approval of the NDA 20-695, and all amendments and supplements thereto, is withdrawn, effective (see DATES).

Distribution of this product in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the act (21 U.S.C. 355(a) and

21 U.S.C.  
331(d)).

see s/c

Dated: 5/31/07  
May 31, 2007.

*[Handwritten Signature]*

D. C. THROCKMORTON  
Douglas C. Throckmorton,  
Deputy Director,  
Center for Drug Evaluation and Research.

CERTIFIED TO BE A TRUE  
COPY OF THE ORIGINAL  
*[Handwritten Signature]*

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