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February 29, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5600 Fishers Lane
Room 4-62
Rockville, Maryland 20857

CITIZEN PETITION

The undersigned submits this petition under 21 CFR 10.25(a), 10.30, and 314.161(b) to determine whether Glaxo Wellcome's ZANTAC 75 EFFERDOSE (ranitidine effervescent tablets 75 mg, ANDA 20-745) is not being marketed due to reasons of safety or efficacy. Reference is also made to Controlled (confidential) Correspondence, Reference Number 98-394, which was issued by the Director of the Office of Generic Drugs (OGD) on 22 December 1998 and to which we are legally privy.

Action Requested

Petitioner understands that the ZANTAC 75 EFFERDOSE has not been marketed despite FDA approval on 26 February 1998. According to FDA's *Approved Drug Products with Therapeutic Equivalents* we see, too, that the NDA for the product has not been withdrawn.

Petitioner requests that the Commissioner, Food and Drug Administration, make a determination whether ZANTAC 75 EFFERVESCENT TABLETS are not being marketed for reasons of safety or efficacy.

Statement of Grounds

The Code of Federal Regulations, 21 CFR 314.161(b) provides that any person may petition under 21 CFR 10.25(a) and 10.30 for a determination whether a listed drug has not been withdrawn from the market for reasons of safety or efficacy. We have determined that the Glaxo Wellcome product is not being marketed, if indeed it was ever marketed at all. Further, in Controlled Correspondence Number 98-394, OGD confirmed that ZANTAC 75 EFFERDOSE was not being marketed at the time the letter was written, and urged the submission of this Petition.

OOP-0842

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Environmental Impact

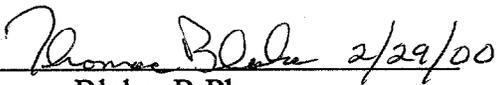
A categorized exclusion under 21 CFR Section 25.23(c) and 25.24(c) is hereby claimed.

Economic Impact

Information under this section will be submitted if requested by the Commissioner upon review of this petition.

Certification

The undersigned certifies that, to the best of his knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petitioner.


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