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Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
HFA-305, Room 1061
5630 Fishers Lane
Rockville, MD 20852

CITIZEN PETITION

The undersigned submits this petition in accordance with 21 CFR §10.20, §10.30, and §314.161 to request the Commissioner of the Food and Drug Administration to provide a determination of reasons for voluntary withdrawal of a listed drug.

A. Action requested

The petitioner requests that the Commissioner of the Food and Drug Administration determine whether Cataflam® (diclofenac potassium) Tablets 25 mg (NDA 20-142), manufactured by Novartis Pharmaceuticals Corporation, have been voluntarily withdrawn or withheld from sale for safety or effectiveness reasons.

B. Statement of grounds

The Food and Drug Administration (FDA) maintains the publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (also referred to as the Orange Book), which lists those drug products that are eligible for submission as abbreviated new drug applications (ANDAs). Although Cataflam® (diclofenac potassium) Tablets 25 mg were the subject of an approved new drug application (NDA 20-142, approved on November 24, 1993), the Orange Book lists Cataflam® (diclofenac potassium) Tablets 25 mg in the Discontinued Section.

As described in 21 CFR §314.162 and in the Orange Book, FDA will remove an approved drug product from the Orange Book when (1) the agency withdraws or suspends approval

2003P-0300 CP1

of an NDA or ANDA, or (2) the agency determines that the drug was withdrawn from sale for safety or effectiveness reasons or that the drug was not marketed.

As of the date of this petition, the petitioner has not determined why Cataflam® (diclofenac potassium) Tablets 25 mg have been listed as discontinued in the Orange Book. The approval of NDA 20-142, under which the product was approved, has not been withdrawn or suspended because Cataflam® (diclofenac potassium) Tablets 50 mg, the other product covered by NDA 20-142, continues to be marketed in the U.S. It is therefore requested that the FDA provide a determination whether Cataflam® (diclofenac potassium) Tablets 25 mg have been withdrawn from sale for reasons of safety or effectiveness.

C. Environmental impact

An environmental assessment report on the action requested in this petition is not required under 21 CFR §25.31.

D. Economic impact

Pursuant to 21 CFR §10.30(b), a statement of the effect of requested action on various economic indicators will be submitted only if requested by the Commissioner.

E. Certification

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

Sincerely,

Nicholas M. Fleischer, R.Ph., Ph.D.
Vice President, Clinical Pharmacology & Biopharmaceutics
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NMF/kh

cc Gary Buehler, Director, Office of Generic Drugs