

SEPTEMBER 19, 2001

DOCCUMENTS MANAGEMENT BRANCH

FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

CITIZEN PETITION

The undersigned submits this petition under CFR §314.161(b) for a determination whether the listed drug ardeparin sodium, Application No. 020227 (Normiflo), hereinafter the "subject drug", has been voluntarily withdrawn for safety or effectiveness reasons.

A. Action requested

The petition requests the Commissioner to cause the subject drug to be relisted as provided in CFR §314.162(c) in order that it be reestablished as a referenced drug for purposes of an abbreviated new drug application (ANDA) pursuant to 21 CFR part 314, subpart C.

B. Statement of grounds

The subject drug, which is a low molecular weight heparin, was approved as a listed drug on the application of Wyeth Ayerst under date of May 23, 1997 as a new chemical entity with an exclusivity date expiring May 23, 2002. The listing did not include a reference to Patent Number 4,757,057 even though the patent was cited in the new drug application of Wyeth Ayerst. This appears to be because the patent is for a method of manufacture and is not a bar to an ANDA according to the provisions of CFR §314.110(b)(2). As originally listed the subject drug was designated a reference listed drug in two dosage strengths.

The Prescription and Over-the-Counter Drug Product List (The List), 20th Edition, Supplement #4, (April, 2000) deletes Wyeth Ayerst as the approved applicant for the subject drug and adds Pharmacia and Upjohn as the approved applicant.

In The List, 21st Edition, Supplement #5, (May, 2001) the subject drug has been omitted in the part that lists approved prescription drugs and is now included in the part

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that lists an approved products which have been discontinued **from** marketing or have had their approval withdrawn for other than safety or efficacy reasons subsequent to being discontinued **from** marketing.

The Federal Register is devoid of any notice that the subject drug was removed **from** The List by the FDA on any grounds described in 21 CFR §3 14.162.

It therefore appears that Pharmacia and Upjohn acquired the right to market the subject drug and withdrew it as a low molecular weight heparin potentially competitive with dalteparin, Application Number 020287 (Fragmin) the listed low molecular weight heparin marketed by Pharmacia and Upjohn. Dalteparin claims patent protection until January 4, 2005.

C. Environmental impact

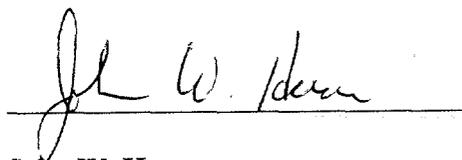
In the Federal Register, May 18, 1998, (Volume 63, Number 95), the Food and Drug administration (Docket No.98N-0286), pursuant to 25 CFR part 25, published its finding of no **significant** impact (FONSI) for the subject drug after review of the environmental assessment.

D. Economic impact

Economic impact data will be submitted upon request 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 that it includes representative data and information known to the petitioner which are unfavorable to the petition.



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