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APPLICATION NUMBER:

17-430/S-026, S-027

CLINICAL PHARMACOLOGY/ BIOPHARMACEUTICS REVIEW(S)

MAR - 4 1999

CLINICAL PHARMACOLOGY/BIOPHARMACEUTICS REVIEW

NDA: 17-430; S-026
NegGram™ (Nalidixic acid) Suspension

SUBMISSION DATE: December 4, 1998

Sanofi Pharmaceuticals, Inc.
90 Park Avenue, 6th floor
New York, NY 10016

REVIEWER: Funmilayo O. Ajayi, Ph.D

TYPE OF SUBMISSION: Labeling Supplement

BACKGROUND: This submission is a response to the Geriatric rule. The labeling supplement is for the Geriatric Use subsection of the product label. No changes are being proposed for the Clinical Pharmacology section of the approved label.

FINDINGS: There is no pharmacokinetic information in the elderly but this drug is known to be excreted primarily via the kidneys. Hence, renal function dysfunction would be expected to cause a reduction of the elimination of nalidixic acid. Although there is no formal study to address the need or lack thereof for dosage adjustment in patients with reduced renal function, a statement under Precautions/General subsection of the product label gave an indication that patients with creatinine clearance as low as 2 - 8 mL/minute have received full dosage without increase in toxicity.

RECOMMENDATION: The submitted information has been reviewed and found acceptable.

APPEARS THIS WAY
ON ORIGINAL

/S/ 3/4/99
Funmilayo O. Ajayi, Ph.D
Div. of Pharmaceutical Evaluation III

FT initialed by Frank Pelsor, PharmD..... /S/ 3/4/99

cc: NDA 17-430 HFD-590 (Clinical Division)
HFD-880 (DPE3,Pelsor,Ajayi)
CDR (Attn: B. Murphy)