



• TRANSMITTED VIA FACSIMILE

NOV 20 2000

Ms. Catherine Clark
Director, NA Regulatory Affairs
SmithKline Beecham Pharmaceuticals
1250 S. Collegeville Road
P.O. Box 5089
Collegeville, PA 19426-0989

RE: **NDA 20-883**
Argatroban Injection (100mg/mL)
MACMIS ID # 9527

Dear Ms. Clark:

This letter addresses SmithKline Beecham Pharmaceuticals (SKB) dissemination of a "reminder" advertisement for Argatroban injection identified as #AR6690. The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed this advertisement as part of its monitoring and surveillance program and has concluded that the advertisement is in violation of the Federal Food, Drug, and Cosmetic Act and applicable regulations.

Reminder advertisements call attention to the name of the drug product, but may not contain written, printed, or graphic matter containing representations or suggestions relating to the drug product. The reminder advertisement for Argatroban injection includes the words, "new" and "introducing," and contains a blood clot graphic. Thus, the advertisement makes a representation about the product.

Promotional materials must also be submitted to DDMAC for review at the time of initial dissemination in compliance with 21 CFR Sec. 314.81. Our records indicate that this promotional material has not yet been submitted for review.

Introducing...



NEW
ARGATROBAN
INJECTION

SB SmithKline Beecham
Pharmaceuticals

AR6690

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