

Food and Drug Administration Rockville MD 20857

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.

DDMAC requests that SKB immediately cease using this advertisement and all other promotional materials for Argatroban that contain the same or similar claims or presentations. You should submit a written response to DDMAC, on or before December 5, 2000, describing its intent and plans to comply with the above. In its letter to DDMAC, you should include a list of all promotional materials that were discontinued, and the discontinuation date.

SKB should direct its response to Patricia Staub by facsimile at (301) 594-6759, or by written communication at the Division of Drug Marketing, Advertising, and Communications, HFD-42; Room 17B-20; 5600 Fishers Lane; Rockville, MD 20857.

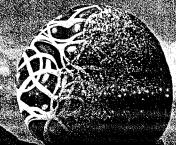
In all future correspondence regarding this matter, please refer to MACMIS #9527 and the NDA number.

Sincerely,

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Patricia Kuker Staub, R.Ph, J.D. Regulatory Review Officer Division of Drug Marketing, Advertising, and Communications

Introducing...



ARGATROBAN

INJECTION

SmrthKline Beechan

AR6690

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