Aventis Pharmaceuticals

July 18, 2001

Sent via fax and UPS

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 01D-0162
Draft Guidance for Industry; Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements [66 FR 20468, April 23, 2001]

Dear Sir/Madam:

Aventis Pharmaceuticals is pleased to have the opportunity to comment on the "Draft Guidance for Industry on Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements". We agree with FDA's position that certain FDA-approved patient labeling can fulfill the brief summary requirement. In fact, well written patient labeling can communicate in consumer language important information that patients need to know to use products appropriately. We offer the following comments/clarification for your consideration.

I. Background

Lines 53-64 - "The Agency believes that approved patient labeling that comprehensively addresses the product's most serious and most common risks is a suitable means of communicating risk information to patients."

The Agency stresses that comprehensive approved patient labeling would be a suitable means of communicating risk information to patients. If the FDA is willing to accept this type of labeling, industry must have assurance that the agency will have adequate resources to perform labeling review in a timely fashion. Additionally, the agency needs to make transparent the review and approval processes for both the patient package labeling and the brief summary.

III. Fulfilling the Brief Summary Requirement

Lines 112-121: "Some examples of products with FDA-approved patient labeling that FDA would not object to for use as a brief summary for DTC print advertisements include...".

01D-0162

C3

Aventis Pharmaceuticals Inc. · Aventis Pharmaceuticals Products Inc. · www.aventis.com
Route 202-206 · PO Box 6800 · Bridgewater, NJ 08807-0800 · Telephone (908) 231-4000

The draft gives some examples of products with FDA-approved patient labeling that would satisfy FDA's information requirements. However, it might be helpful if FDA could provide a general template that it would consider acceptable.

Aventis would also like the Agency to clarify the following – If consumer language based brief summaries are being created solely for DTC advertisements would the consumer language based brief summaries become a mandatory part of the package labeling? Would it then need to be reviewed by both DDMAC and the Review Division?

On behalf of Aventis Pharmaceuticals, we appreciate the opportunity to comment on "Draft Guidance for Industry on Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements" and thank you for your consideration.

Sincerely,

James Boyd

James Boyd, Ph.D., MBA
N.A. Regulatory Center Head
Global Drug Regulatory Affairs

MAILROOM
(908) 231-2192
AVENTIS PHARMACEUTICALS
BUILDING/O-197 (DOCK)
BRIDGEWATER NJ 08807-5007

1 LBS 1 OF 1
DWT: 16,13,1

SHIP TO:
FDA ADMIN.
DOCKET MANAGE. BRANCH
ROOM 1061
5630 FISHERS LANE
ROCKVILLE MD 20853

MD 207 9-01

UPS NEXT DAY AIR S VER 1P

TRACKING #: 1Z 2XX 118 29 4289 0 42

BILLING: P/P
SIGNATURE REQUIRED

UOW 3.1.2 UPS Ther 11.0A 11/2000

Worldwide
Olympic Partner