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30TH DISTRICT, NEW YORK

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BENEFITS



Congress of the United States -2 A10 :49

House of Representatives  
Washington, D.C. 20515-3230

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September 26, 2000

Ms. Janice Oliver  
Food and Drug Administration  
Department of Health and Human Services  
5630 Fishers Ln, Rm 1061  
Rockville, Maryland 20857-0001

Dear Ms. Oliver:

I am writing to encourage the Food and Drug Administration (FDA) to expedite the publication for public comment of the petition filed with FDA on February 17, 2000, by the National Yogurt Association (NYA) to revise the Federal standard of identity for yogurt.

Based on information I have received, NYA has proposed a revision which would enhance the current yogurt standard, while clarifying that yogurt is a food product containing a minimum level of specific live and active cultures. The proposed standard takes into account current industry practices and recognizes the need to allow for the use of future technologies. This proposed standard establishes a clear, consistent, modern, and flexible yogurt standard that will benefit both industry and consumers.

I would appreciate any information you may have regarding this matter. Please feel free to contact Cassandra McClam in my Washington Office regarding this matter. Thank you in advance for your time.

Very truly yours,

  
Jack Quinn  
Member of Congress

JQ:sg

00P-0685

C3

**Aventis Pharmaceuticals**



Sent via fax and UPS

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October 26, 2000

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

Re: Docket No. 00N-1364  
Prescription Drug User Fee Act (PDUFA)

Dear Sir/Madam:

Aventis Pharmaceuticals is submitting this set of comments on the Prescription Drug User Fee Act (PDUFA) in response to the Federal Register notice of August 4, 2000. We are submitting comments to the four specific sets of questions posed by the Agency.

1. Since 1993 FDA has been receiving fees for the review of certain human drug and biological products. As a result, FDA has implemented management improvements that have substantially decreased the time for new drug review and made new medications available to the public faster. Do you view this as a benefit of the user fee program that should be maintained in the future? What are some of the other benefits that you think are important? How do you think the program can be strengthened? In addition, what do you see as the downside of a regulatory agency like FDA collecting user fees and what remedies would you propose for the future?

Aventis believes that the benefits of the User Fees program should be maintained. This program has been successful in terms of more drugs being approved and at a faster rate. This is a significant benefit to patients awaiting new treatments. The program has also made the review process more transparent and consistent. However, these aspects still need to be strengthened, in particular, the consistency of working across all divisions and in the advisory committee process. Another area that could be strengthened is electronic submission, in particular, e-mail communications. The program can be further strengthened by increasing User Fees as necessary to maintain or increase performance goals. The ability for very innovative therapies for unmet needs and orphan drugs to be exempted from fees needs to be retained and an open mind should be maintained with regard to other possible exemptions.

2. Should we continue to have performance goals for the drug and biological review process? If so, how should goals be determined?

Performance goals should be maintained and are essential to monitor the time from submission to approval and the percentage of products approved in the initial review time. There are other things that could be measured; however, they should be kept to a minimum. Performance goals were developed by the agency with contribution from the pharmaceutical companies. It should be considered whether there is any merit to involving other groups such as patient representative groups in this process. Goal accomplishment should be transparent to the public and should be used as part of the internal performance management review process of the individual reviewers. As in industry, salary increases could be tied to meeting personal and overall FDA goals including adherence to defined processes, meeting review times and raising issues and questions as early as possible and following them to conclusion in a timely manner.

3. If user fees fund FDA's drug and biological review processes, what percentage of the program's costs should be covered by fees, and how should those fees be used? (table on pg. showing the percent of drug and biological review spending funded by industry fees since the beginning of PDUFA in 1993)

Regarding the use of the fees, we believe they should be used for the review process. It is possible that User Fees could cover an increasing percentage of review (up to 100%) as long as the process is transparent and the established goals are monitored. Fees for IND submission should also be considered to improve the IND process (i.e., faster review, meetings to discuss the development path). We believe it is necessary to have exemptions from User Fees so as not to prevent innovation and smaller/niche products coming to the market. We believe the cost of these exemptions should be covered by appropriations.

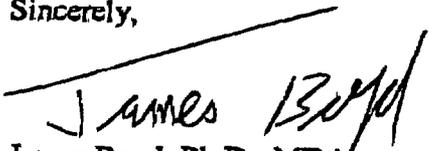
4. Should Fees be collected from industry be used to pay for other costs FDA incurs to ensure that drugs in the American marketplace are safe and effective? Such additional costs might include monitoring adverse drug reactions, monitoring drug advertising, and routine surveillance, inspection and testing of drug manufacturers?

We believe such other activities should be funded by federal appropriations.

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On behalf of Aventis Pharmaceuticals, we appreciate the opportunity to comment on the Prescription Drug User Fee Act (PDUFA) and thank you for your consideration.

Sincerely,

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

Aventis Pharma AG, the pharmaceutical company of Aventis S.A., (NYSE: AVE), is dedicated to treating and preventing human disease through the discovery, development, manufacture, and sale of innovative pharmaceutical products aimed at satisfying unmet medical needs. Aventis Pharma focuses on important therapeutic areas such as cardiology, oncology, infectious diseases, arthritis, allergies and respiratory disorders, diabetes, and central nervous system disorders. The corporate headquarters of Aventis Pharma is in Frankfurt, Germany. In North America, Aventis Pharmaceuticals conducts the business of Aventis Pharma AG.