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NF file
Olestra mm.
SENT TO RACHEL HART - THANKS V.J. BLACKBURN

OLESTRA FILE

January 26, 1996

Henry Blackburn M.D.
P.O. Box 1825
Anna Maria, FL 34216

Dear Dr. Blackburn:

I am delighted that you have agreed to prepare a piece for our Sounding Board section on the FDA's action in approving Olestra. As I mentioned to you, Walt Willett told us that you had been as disturbed by the approval process as by the outcome. It would be useful to our readers to learn something of that process. The manuscript should be no longer than 2000 words, and we will expect it within the next couple of weeks. As always, we can make no commitment to publish even a solicited article until we have had a chance to see it, but we promise a rapid decision.

Sincerely yours,

Marcia Angell

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May 21, 1997

✓ Mailed w/enc.

The Honorable Donna Shalala
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Dear Dr. Shalala:

I have served for two years on the FDA Dietary Advisory Committee. You may or may not have noted my concerns about FDA procedures as expressed in the enclosed editorial on olestra. I can report that the situation has not changed. There are many excellent things going on in the FDA. But one of them is not recognition of the balance needed both organizationally and in terms of skills and staffing, a balance between bench science, clinical science, and epidemiology/public health science. For example, with the new CFSAN center being opened in Maryland, there is simply no organizational component that represents public health science for a function that is primarily concerned with the public health. I can assure you from frequent contact with FDA staff that they are competent in their fields of toxicology and drug trials. But they have systematically not given recognition in their organization chart, in staffing and advisory committee structures, or in concepts, to population views and public health concerns, or to the skills and approaches needed to deal with chronic low dose exposures, such as diet and eating patterns, or with population-based surveillance and other mass phenomena.

I would hope you might agree that these views and skills are needed throughout the agency and that a new FDA Commissioner should understand these needs and possess these broader views. It is also crucial that the Commissioner has no formal ties to industry, so that his views will be credibly independent.

Cordially,

Henry Blackburn

Henry Blackburn, MD
Mayo Professor of Public Health, Emeritus

Enclosure

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