



DEPARTMENT OF HEALTH & HUMAN SERVICES

HFA - 224

Food and Drug Administration  
Rockville MD 20857

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November 29, 2000

The Honorable Jack A. Brown  
Senate Minority Leader  
Arizona State Senate  
Capitol Complex, Senate Building  
Phoenix, Arizona 85007-2890

Dear Mr. Brown:

This is in response to your letter to the Secretary of Health and Human Services, on behalf of one of your constituents, about a pending proposed rule to change federal hearing aid regulations.

In 1993, the Food and Drug Administration published an Advanced Notice of Proposed Rulemaking in the *Federal Register* to revise its regulations. One concern was the number of hearing aid purchasers who waived the current requirement for a hearing aid evaluation. Manufacturers, medical professionals, consumers, and hearing aid dispensers have commented on the rulemaking notice in writing and in meetings, but FDA has yet to publish a proposal.

Your letter has been added to docket #93N0372, which was set up to receive written comments on the 1993 notice. According to rulemaking procedures, neither FDA nor the Department of Health and Human Service can comment on what the proposal may or may not contain until after it publishes.

Sincerely,

Linda Gangloff  
Policy Analyst  
Executive Secretariat

93N-0372

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/ANS

