



DEPARTMENT OF HEALTH & HUMAN SERVICES

HFA - 305
J. Butler

Food and Drug Administration
Rockville MD 20857

December 26, 2000

DEC 28 4:17 PM '00

The Honorable Charles W. Shields
State Representative
201 West Capitol Avenue, Room 101E
Jefferson City, Missouri 65101-6806

Dear Mr. Shields:

This is in response to your letter, on behalf of Mark States, 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

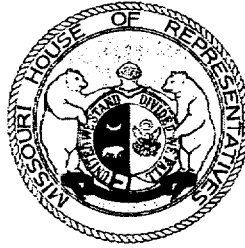
93N-0372

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CHARLES W. SHIELDS
State Representative
District 28

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November 27, 2000

Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Sir/Madam:

Enclosed is a copy of a letter from our constituent expressing concerns regarding the proposed rule to revise the way hearing aids are sold.

Please look into this situation and send our office information regarding this change and why it was done. It seems that this ruling will put many licensed hearing specialists out of business.

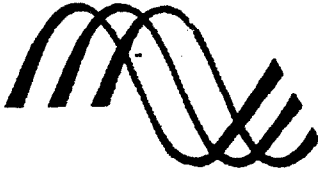
Thank you for your consideration and I look forward to your prompt reply.

Sincerely,

A handwritten signature in cursive script that reads "Charles Shields".

Charles W. Shields





Miracle-Ear

**States Hearing Aid Center, Inc.
515 S. Belt Hwy.
St. Joseph, MO, 64506
816-233-8011
Fax 816-232-9204**

COPY

Wednesday, October 18, 2000

Dear Representative Charlie Shields

Charlie, I am deeply concerned that the government may put me out of business and I'm writing to you for your assistance.

As a Missouri licensed hearing instrument specialist and operating a small business in northwest Missouri and serving thousands of hearing impaired persons. The Food and Drug Administration is now, after seven years of inaction, rushing to publish a proposed rule to revise the way hearing aids are sold in this country. The FDA is reportedly planning to allow the states to pick and choose which tests must be required before a hearing aid can be purchased and which hearing health providers are qualified to conduct such tests.

Presently, hearing instrument specialist, physicians, and audiologists are essential and fully qualified entry points into the health care system. If the FDA defers to states, audiologists have indicated that they would endeavor to position themselves as the sole entry point into hearing health care. Such gatekeeper status could be achieved by lobbying states to require expensive hearing tests that only audiologists provide. This would not only force hearing instrument specialists such as myself out of business, but it would greatly increase costs and impede access to hearing health care services for the nation's hearing impaired.

Hearing impairment is a major health care concern. Please don't let the FDA propose this new rule. It's bad for the hearing impaired and bad for small business hearing health providers. Please write the President and the Secretary of Health urging that this proposed rule be rejected. I would greatly appreciate a copy of any letter you send on behalf of me and the hearing impaired that I serve.

Respectfully yours,

Mark W. States,
Board Certified Hearing Instrument Specialist