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April 15, 2003

Marlene H. Dortch, Secretary
Federal Communications Commission
Washington, DC 20554

Re: Report of Ex Parte Communication
WT Docket No. 01-309

Dear Ms. Dortch:

Pursuant to Section 1.1206(a)(2) of the Commission's Rules, this is to report that the attached *ex parte* **written communication** was submitted to Ms. Mindy Littell of the **Wireless Telecommunications Bureau** today by the **Hearing Industries Association**.

Respectfully submitted,

Peter Tannenwald
Counsel for the Hearing Industries Association

cc: (w/o att) (by-mail)
Mindy Littell, Esq.
Ms. Carole Rogin

HEARING INDUSTRIES ASSOCIATION

April 15, 2003

Ms. Mindy Littell
Federal Communications Commission
Wireless Telecommunications Bureau, Policy Division
445 12th Street, SW
Washington, DC 20554

Dear Ms. Littell:

I am forwarding the two documents that you requested yesterday:

- FDA's Guidance to Hearing Aid Manufacturers for Substantiation of Claims
- HIA's Guidelines for Hearing Aid Manufacturers for Substantiation of Performance Claims

Please let me know if you need additional information.

Sincerely,
Carole M. Rogin
Executive Director

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Guidelines for Hearing Aid Manufacturers for Substantiation of Performance Claims

Hearing Industries Association
November 26, 2002

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PREFACE

These Guidelines are designed to assist manufacturers in understanding and identifying the substantiation requirements for hearing aid claims, including performance or user-benefit claims. As part of that goal, these Guidelines outline a protocol that a manufacturer may follow to obtain scientific data to substantiate claims. Labels, labeling, brochures and other similar materials are promotional materials, and like advertising, claims made in these materials create substantiation requirements under the United States Food and Drug Administration's ("FDA's") and the Federal Trade Commission's ("FTC's") laws. Importantly, every claim requires some level of substantiation and the manufacturer must possess the substantiation at the time a claim is made.

To determine the appropriate substantiation for a claim, identifying the claim made is critical. Claims may be explicit or implicit, and a manufacturer is responsible, and subject to exposure, for both types. Moreover, when a claim is ambiguous, the manufacturer is charged with responsibility for all claims made, whether intended or not. Thus, promotional materials may contain multiple claims, all of which must be covered by substantiation that is appropriate for the claim made.

Endorsements or testimonials are popular mechanisms for promoting hearing aids. These communication techniques create at least two claims and thus two substantiation requirements. First, the endorser's statements must be true. Second, the endorsement also carries a typicality claim. No one would present an endorsement to communicate a solitary experience. Thus, a broader substantiation requirement than one person's experience emerges. In other words, not only does the manufacturer need to demonstrate the truthfulness of the endorsement or testimonial, but the manufacturer must have substantiation for the claim that the consumer's experience is typical.

These Guidelines serve yet another function: they provide a basis for hearing aid manufacturers to privately resolve disputes about promotional claims. HIA's Advertising Task Force developed these Guidelines as a consensus document that will assist in mediating disputes between members. By setting forth reasonable substantiation principles, the Guidelines provide a yardstick against which substantiation can be measured. As a result, there will be no surprises about the standard applied to evaluating substantiation, particularly substantiation for Type 3 claims. The intent behind private dispute resolution is to encourage the hearing aid industry to self-police and develop acceptable and useful claims and substantiation principles. This approach is preferable to government investigations of manufacturers' promotional materials and judgments about hearing aid capabilities that in the past have been considered to be ill conceived.

Carole Rogin
Executive Director, HIA

INTRODUCTION

A. These Guidelines present a protocol for performing evaluations of hearing aids for the purpose of obtaining scientific data to substantiate user-benefit claims of all types. Other types of scientific evidence, such as reference to published research, surveys, or controlled physical measurements may be more appropriate for some user-benefit claims.

B. Three types of user-benefit claims may be made by a manufacturer that would allow or require different techniques of substantiation.

Type 1. Performance claims that are generally accepted by the clinical and user communities. Type 1 claims require minimal substantiation. Examples are "many hearing aid wearers find that it is easier to communicate with friends and family" and "so tiny, only you may know it's here."

Type 2. Performance claims that are supported by information valid for the device in the context of the claim. Substantiation may be in the form of clinical data, bench data, journal articles, etc. that support the claim. For example, a manufacturer may use a journal article if it addresses the claim at issue and provides valid scientific evidence that the claim is true. Substantiation data are to be kept at the manufacturing facility. Examples of Type 2 claims are "Class D hearing instruments have been shown to have better sound quality than Class A devices" and "the circuit helps to make soft sounds audible and loud sounds comfortable."

Type 3. Performance claims involving improved speech recognition in noise. Substantiation should be in the form of data obtained using the protocol outlined in these Guidelines for speech-in-noise claims. Substantiation data are to be kept at the manufacturing facility. Examples are "for many people, speech understanding in group situations will be much easier" and "the circuit is an environmentally-adaptive processor."

C. These Guidelines may be revised from time to time as changes in technology warrant or as new scientific information becomes available. Manufacturers are encouraged to bring updated information to HIA if evidence exists which may affect the contents of this protocol.

D. A manufacturer may apply Type 3 claims to its revised hearing aid when the design, performance specifications, and performance of the revised and the original hearing aids are essentially equivalent, with the revised device's performance at least equaling that of the original device. To the extent the manufacturer makes superiority or new claims for its revised hearing aid, additional substantiation is required. When such a new representation is a Type 3 claim, the substantiation recommendations in these Guidelines are applicable.

E. A manufacturer who chooses to follow a different protocol other than that recommended in these Guidelines should prepare a position paper that clearly explains and defends the merits of the alternative course of action.

GENERAL REQUIREMENTS

A. Substantiation of Type 2 and 3 user-benefit claims will be based on controlled clinical studies using acknowledged, reliable and valid scientific and clinical measures.

B. Both objective (e.g., speech recognition or speech reception threshold in noise measures, such as NU-6, SPIN, SIN, or HINT) and subjective (e.g., self-assessment scales of benefit, satisfaction, or sound quality, including the APHAB, COSI, SADL, or IOI-HA) standard measurements may be included as substantiation for Type 2 and 3 user-benefit claims. Non-standardized test measures are discouraged and should be avoided, particularly for subjective assessments. Additionally, when objective and subjective data provide discrepant results, the primary data used for Type 3 performance claims should be objective data, which minimize the potential for experimental bias.

STUDY SITES

A. Data may be collected for substantiation of Type 2 claims using one study site. Type 3 studies will be conducted at a minimum of two autonomous sites, with independent principal investigators; however, only one of these sites may be a manufacturer's facility or facility in which the manufacturer has a financial stake, and the statistical determination of benefit should be evaluated consistent with the principles in Statistical Analysis ¶ B, below.

B. In conducting Type 2 and 3 studies, data may be evaluated in several daily life situations utilizing one of several test instruments for which normative data are available.

STUDY POPULATION / PATIENT SCREENING

A. Subjects for Type 2 and 3 studies will have auditory characteristics/behavior appropriate for the intended claim of the device being investigated. For example, for a high gain and output hearing aid, the subjects selected for the investigation should have severe or profound - and not mild - hearing loss.

B. The Study population for Type 2 and 3 studies will be fully described according to:

1. Number of subjects
2. Gender of subjects
3. Ages of subjects
4. Audiogram configurations
5. Type of hearing loss
6. Prior amplification experience
7. Pertinent lifestyle considerations
8. Ethnic background
9. Native language

Additional descriptors of the study population may be reported, including classification by auditory or non-auditory characteristics, site-of-lesion, etiology, etc., as desired.

C. As a general principle, the audiological tests and measurements required to be administered to a subject when behavioral tests are used will be determined by the nature of the claim and the technology under investigation. At a minimum, the following tests will be performed: pure-tone air-conduction thresholds at octave intervals from 250 Hz to 8000 Hz; pure-tone bone-conduction thresholds at octave frequencies from 250 Hz to 4000 Hz; speech reception thresholds; speech recognition testing on a standardized, norm referenced speech recognition test; and the immittance test battery.

D. Description of the dynamic range, most comfortable range, and loudness discomfort levels may be included if relevant to the aims of the study.

E. Informed consent shall be obtained from each subject.

F. Each manufacturer must assess whether it is subject to the Health Insurance Portability and Accountability Act (HIPAA) of 1996. If so, patient (subject) information should remain confidential in accordance with HIPAA.

INCLUSION AND EXCLUSION CRITERIA

A. When Type 2 and 3 studies are conducted, describe inclusion and exclusion criteria. Subjects will be selected for the investigations who have auditory characteristics that are relevant to the device or characteristic being studied.

B. Subjects with eighth nerve tumors should be excluded. Subjects with histories of known fluctuating hearing loss, or rapidly progressing hearing loss should be excluded, but may be included when the technology under study is specifically designed for these conditions.

C. Subjects should be in good health (e.g. capable of completing the study).

STUDY DESIGN

A. For all studies, the research strategy and experimental design selected to substantiate a claim should be appropriate to properly evaluate the characteristic, feature or instrument that is being investigated.

B. For Type 2 and 3 behavioral studies, any design that is going to be used will be fully described and justified.

C. The number of subjects required for a given Type 2 or 3 behavioral study will be ascertained with appropriate statistical power analysis. Subjects may be used as their own controls. The general recommendation is to start with at least 25 subjects per site, with the goal of having at least 20 subjects per site complete the study.

D. In Type 2 and 3 studies, the following procedural elements will be included and reported:

1. The number of investigators, the number of sites, and ability of the investigators to meet the requirements of the study;

2. A complete description of all measurements made, the procedures used in making the measurements, a complete description of the environment(s) in which the testing was conducted and a detailed description of the measurement and experimental instrumentation involved in the study;

3. Masking (blinding) is always considered appropriate in any clinical study in order minimize bias. If this ideal cannot be achieved, a full description of expected biases and the methodology used to minimize the biases will be provided;

4. If speech testing is employed, norm-referenced, standardized speech testing materials will be used, and estimates of test-retest reliability and alternate form equivalency reported;

5. Test contents, materials and method of delivery/administration will be fully described and their use justified. The experimental design should not solely use laboratory conditions configured to maximize benefit and set false expectations regarding user benefit. In other words, the experimental design should not use idealized conditions that exaggerate favorable results. Examples are:

a. For speech understanding in noise using a fixed signal-to-noise ratio (SNR), at least one condition should be set near 0 dB SNR to insure that the benefit is not audibility but indeed speech understanding in noise.
b. For directional microphone investigations, at least one condition should utilize a balanced (e.g. diffuse) masking field with equal energy right-to-left and front-to-back with regards to the subject position.
c. For noise reduction investigations, at least one condition should utilize a broadband, preferably spectrally matched, masker.
d. For multiple loudspeaker arrays, at least one condition should utilize uncorrelated maskers.

6. In investigations of speech recognition in noise, self-report inventories of subject satisfaction, attributes of satisfaction, use, benefit in daily life situations will be included in order to assess those properties outside of the laboratory setting. Test instruments for which normative data are available should be used, with their selection justified;

7. A study will last a minimum of 30 days to ensure that subjects have had enough time to wear the device in a variety of listening environments so they may report their experiences to the investigator;

8. If the investigator wishes to measure the subject's perception of the quality of sound of the hearing aid(s) (such as clarity, comfort, pleasantness, and lack of hollowness, etc.), they will be measured through use of standardized questionnaires;

9. Whether the investigation was performed monaurally or binaurally and, if monaural, whether the non-test ear was occluded will be reported;

10. The presence and type of earmold and venting utilized, the method of setting the volume control, whether the volume control was allowed to be fixed or varied, and the methods for and setting of each instrument control for all conditions will be documented in a detailed manner (for both the test instrument and any control instrument that is used). Care will be taken to ensure that the same fitting procedures are followed at all study sites;

11. Whether or not aided vs. unaided testing was incorporated, and whether a comparison to a control aid was made, will be reported;

12. Graphic presentation of data should be utilized to enhance the description of the data;

13. If a claim is made to compare a new technology hearing aid versus one that is currently being worn by a subject, the study design must include adequate controls for making the comparative analysis;

14. Acclimatization effects may be included as an option of the study design; and

15. For Type 3 claims, and Type 2 claims which require clinical substantiation, manufacturers must supply scientific data from studies of their own hearing aids to substantiate their individual claims. Manufacturers may not rely on studies done by others on hearing aids similar to their hearing aid, but instead should conduct clinical studies of their own products.

QUALITY CONTROL

A. All hearing aids used in studies will be measured using ANSI S3.22-1996 procedures, and ANSI S3.42-1992 when broadband noise signals are employed as part of the experimental process. Probe microphone measurements will be made in accordance with ANSI S3.46 1997. If additional electroacoustic measurements detailing the performance of the instrumentation are used in the study, they will be reported.

B. In Type 2 and 3 behavioral studies, the method utilized for selecting, fitting and adjusting the hearing aids to the subjects will be reported and justified on the basis of its relation to the objectives of the study. An appropriately fitted hearing aid depends upon the technology used, the type of hearing loss involved, the fitting methodology employed and the objectives of the study as developed by the investigators.

C. The experimenter will verify that the performance of the hearing aids under study remain stable throughout the test period; e.g., that no control or other settings were altered from the specified settings.

D. The test subjects' audiometric thresholds will be evaluated at the end of the study. Data from subjects whose audiometric thresholds have significantly changed from the beginning of the study will be excluded from final analysis.

SUBJECT DISCONTINUATION

The experimenter will anticipate an expected number of losses in Type 2 and 3 studies, and should design for such an occurrence. Subjects who discontinue should be accounted for in the report including identifying the reason(s) for discontinuation.

SUBJECT COMMENTS

In Type 2 and 3 studies, favorable and unfavorable comments by subjects during the course of the study will be recorded and reported.

STUDY ENDPOINTS

A. The endpoint of a study design will have a direct focus on the claim that is being evaluated.

B. The performance claim(s) in question will be contained in the hypotheses of the experiment, and the endpoint(s) expressed as support either for or against the hypotheses.

C. In Type 2 and Type 3 studies, appropriate data may be reported to support claims of few (0-25%), some (26-50%), many (51-75%), or most (76-100%) wearers who would be expected to gain benefit.

STATISTICAL ANALYSIS

A. For Type 2 and 3 studies, results of clinical tests will be statistically analyzed in support of substantiation of the claims being made. Statistical analyses will use appropriate (e.g., normal, binomial, etc.) distributions with *p* values no greater that 0.05 as determinants of statistical significance.

B. For Type 3 studies, conclusions of benefit may be determined utilizing (a) independent analyses of the multiple research sites, or (b) pooled subject analysis across research sites, provided statistical analysis (ANOVA) does not show a significant interaction of site vs. main effect. That is, if there is a significant interaction between a site and main effect, the claim(s) may not be made.

C. The sponsor will determine the level of improvement needed for a clinically significant change to occur in the study. The method used to determine this level will be described and justified.

03P378

Guidance to

Hearing Aid Manufacturers

for

Substantiation of Claims

Food and Drug Administration
Center For Devices and Radiological Health
Office of Device Evaluation
Division of Reproductive, Abdominal, Ear, Nose
and Throat, and Radiological Devices

August 5, 1994

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INTRODUCTION

A. A protocol is presented for performing evaluations of hearing aids for the purpose of obtaining scientific data to substantiate user-benefit claims of all types. Other types of scientific evidence, such as reference to published research, surveys, or controlled physical measurements may be more appropriate for some user-benefit claims.

B. Two types of user-benefit claims may be made by a manufacturer that would allow or require different techniques of substantiation.

> Type 1. Technical performance claims. These are claims about the technical performance of the hearing aid that can be substantiated solely with electroacoustic laboratory bench tests, involving quantitative determinations using measurements, for example, per ANSI standards S3.22, S3.35 S3.42, or other electrical, mechanical and/or acoustical tests.

> Type 2. Wearer benefit claims. These are claims about how the performance of the hearing aid may benefit or improve the performance of the wearer. These claims require the use of human subjects for the substantiation of the claim, and may or may not be accompanied by (Type 1) technical performance measurements.

C. This guidance document may be revised from time to time as changes in technology warrant or as new scientific information becomes available. Manufacturers are encouraged to bring updated information to the FDA if evidence exists which may affect the contents of this protocol.

D. Manufacturers who choose to depart from the guidance presented in this protocol are strongly encouraged to discuss these changes with FDA.

E. Manufacturers who choose to follow a different statistical protocol other than that recommended in the attached memo should submit a position paper to FDA that clearly explains and defends the merits of the alternative course of action. Following agency review, a meeting may be requested at FDA to discuss the merits of the alternative protocol.

GENERAL REQUIREMENTS

A. Substantiation of Type 2 user-benefit claims will be based on controlled clinical studies using acknowledged, reliable and valid scientific and clinical measures.

B. Both objective and subjective data may be included when substantiating Type 2 user-benefit claims.

STUDY SITES

A. Data may be collected for substantiation of Type 1 claims using one study site. Type 2 studies will be conducted at a minimum of two independent sites, one of which may be a manufacturer's facility.

B. In conducting Type 2 studies, data may be evaluated in several daily life situations utilizing one of several test instruments for which normative data are available.

STUDY POPULATION/PATIENT SCREENING

A. Subjects for Type 2 studies will be selected dependent upon the claims of the technology of the device under investigation. The study population should include subjects who have auditory characteristics/behavior for which the feature or device being studied is intended.

B. The study population for a Type 2 study will be fully described according to:

(1) Number of subjects
(2) Gender of subjects
(3) Ages of subjects
(4) Audiogram configurations
(5) Type of hearing loss
(6) Prior amplification experience
(7) Pertinent lifestyle considerations
(8) Ethnic background
(9) Native language

Additional descriptors of the study population may be reported, including classification by auditory or non-auditory characteristics, site-of-lesion, etiology, etc., as desired.

C. As a general principle, the audiological tests and measurements required to be administered to a subject when behavioral tests are used will be determined by the nature of the claim and the technology under investigation. At a minimum, the following tests will be performed: pure-tone air-conduction thresholds at octave intervals from 250 Hz to 8000 Hz; pure-tone bone-conduction thresholds at octave frequencies from 250 Hz to 4000 Hz; speech reception thresholds; speech recognition testing on a standardized, norm referenced speech recognition test; and the immittance test battery.

D. Description of the dynamic range, most comfortable range, and loudness discomfort levels may be included if relevant to the aims of the study.

E. Informed consent should be obtained from each subject.

INCLUSION AND EXCLUSION CRITERIA

A. When Type 2 studies are conducted, describe inclusion and exclusion criteria. Subjects will be selected for the investigation that have auditory characteristics that are relevant to the device or characteristic being studied.

B. Subjects with eighth nerve tumors should be excluded. Subjects with histories of known fluctuating hearing loss, or rapidly progressing hearing loss should be excluded, but may be included when the technology under study is specifically designed for these conditions.

C. Subjects should be in good health (e.g. capable of completing the study).

STUDY DESIGN

A. For all studies, the research strategy and experimental design selected to substantiate a claim should be appropriate to properly evaluate the characteristic, feature or instrument that is being investigated.

B. For Type 2 behavioral studies, any design that is going to be used will be fully described and justified.

C. The number of subjects required for a given Type 2 behavioral study will be ascertained with appropriate prospective analysis. Subjects may be used as their own controls.

D. In Type 2 studies, the following procedural elements will be included and reported:

(1) The number of investigators, the number of sites, and the ability of the investigators to meet the requirements of the study;

(2) A complete description of all measurements made, the procedures used in making the measurements, a complete description of the environment(s) in which the testing was conducted and a detailed description of the measurement and experimental instrumentation involved in the study;

(3) Masking (blinding) is always considered appropriate in any clinical study in order to minimize bias. If this ideal cannot be achieved, a full description of expected biases and the methodology used to minimize the biases will be provided;

(4) If speech testing is employed, norm-referenced, standardized speech testing materials will be used, and estimates of test-retest reliability and alternate form equivalency reported;

(5) Test contents, materials and method of delivery/administration will be fully described and their use justified;

(6) In investigations of speech recognition in noise, self-report inventories of subject satisfaction, attributes of satisfaction, use, or benefit in daily life situations will be included in order to assess those properties outside of the laboratory setting. Test instruments for which normative data are available should be used, with their selection justified;

(7) A study will last a minimum of 30 days to ensure that subjects have had enough time to wear the device in a variety of listening environments so they may report their experiences to the investigator;

(8) If the investigator wishes to measure the subject's perception of the quality of sound of the hearing aid(s) (such as clarity, comfort, pleasantness, and lack of hollowness, etc.), they will be measured through use of questionnaires;

(9) Whether the investigation was performed monaurally or binaurally and, if monaural, whether the non-test ear was occluded will be reported;

(10) The presence and type of earmold and venting utilized, the method of setting the volume control, whether the volume control was allowed to be fixed or varied, and the methods for and setting of each instrument control for all conditions will be documented in a detailed manner (for both the test instrument and any control instrument that is used). Care will be taken to ensure that the same fitting procedures are followed at all study sites;

(11) Whether or not aided vs. unaided testing was incorporated, and whether a comparison to a control aid was made, will be reported;

(12) Graphic presentation of data should be utilized to enhance the description of the data;

(13) If a claim is made to compare a new technology hearing aid versus one that is currently being worn by a subject, the study design must include adequate controls for making the comparative analysis;

(14) Acclimatization effects may be included as an option of the study design; and

(15) Manufacturers must supply scientific data from studies of their own hearing aids to substantiate their individual claims. Manufacturers may not claim substantiation merely on the basis of offering a level of technology similar to that being offered by other firms.

QUALITY CONTROL

A. All hearing aids used in Type 1 and Type 2 studies will be measured using ANSI S3.22-1987 procedures, and ANSI S3.42-1992 when broad band noise signals are employed as part of the experimental process. If additional electroacoustic measurements detailing the performance of the instrumentation are used in the study, they will be reported.

B. In Type 2 behavioral studies, the method utilized for selecting, fitting and adjusting the hearing aids to the subjects will be reported and justified on the basis of its relation to the objectives of the study. An appropriately fitted hearing aid depends upon the technology used, the type of hearing loss involved, the fitting methodology employed and the objectives of the study as developed by the investigators.

C. The experimenter will verify that the performance of the hearing aids under study remain stable throughout the test period; e.g., that no control or other settings were altered from the specified settings.

D. The test subjects' audiometric thresholds will be evaluated at the end of the study. Data from subjects whose audiometric thresholds have significantly changed from the beginning of the study will be excluded from final analysis.

SUBJECT DISCONTINUATION

The experimenter will anticipate an expected number of losses in Type 2 studies, and should design for such an occurrence.

SUBJECT COMMENTS

In Type 2 studies, favorable and unfavorable comments by subjects during the course of the study will be recorded and reported.

STUDY ENDPOINTS

A. The endpoint of a study design will have a direct focus on the claim that is being evaluated.

B. The claim(s) in question will be contained in the hypotheses of the experiment, and the endpoint(s) expressed as support either for or against the hypotheses.

C. In Type 1 and Type 2 studies, appropriate data may be reported to support claims of few (0-25%), some (26-50%), many (51-75%) or most (76-100%) wearers who would be expected to gain benefit.