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November 7, 1994

X-----

Re: X-----
Speech Therapy Device

Dear X-----,

I am responding to your letter to the Legal Division dated July 15, 1994. You are following up on my letter to you dated August 23, 1994, in which I concluded that X-----'s 'product is a "device" excluded from the definition of "medicine" under Regulation 1591(c) (2). I indicated in that letter that you had not included a description of the Biofeedback System and how it operates. You included with your new letter a brochure describing the System.

You describe the Biofeedback system as "a speech aid for the hearing impaired- specifically persons with developmental stuttering [¶] ... Persons who stutter have perfectly healthy lungs, vocal folds, jaws, tongues, lips, etc. Stuttering is a disorder of the brain, in its ability to coordinate the above organs to produce speech. Consequently, you could say that my product primarily assists the brain "

The brochure describes the Biofeedback System as follows:

"The biofeedback system provides electromyograph-controlled fluency-enhancing auditory feedback to enable fluency and train users to talk with relaxed speech-production muscle tension.

* * *

"Electromyography (EMG) measures muscle tension. EMG biofeedback is widely used for neuromotor rehabilitation, muscle re-education, and psychotherapy.

* * *

"The user wears a headset with microphone and headphones, and tapes three EMG electrodes to his or her neck or jaw. The biofeedback system is 10 x 8 x 3 inches, the size of a laptop computer.

“When the user's speech-production muscles and breathing are relaxed, the biofeedback system shifts his or her voice in the headphones lower in pitch. This enables fluency and awareness of muscle tension.

“When the system senses increasing muscle tension before a stuttered block, it raises the pitch of the user's voice in the headphones, suggesting that the user relax.

“If the user stutters, the system raises the pitch higher and pulls the user out of the block.”

You also sell the system without the EMG technology, which enables fluency while wearing the headphones but users revert to stuttering when the headphones are off. The brochure further indicates that an optional miniature in-ear headphone and microphone suitable for job interviews or public speaking is available. It also indicates that your company is developing a pocket--size fluency aid which does not have the EMG system. The picture in the brochure shows a laptop-computer-sized processor with the user wearing a headphone and electromyograph electrodes. You indicate in your letter you have developed a new system which is the size of a Walkman personal stereo and is fully worn on the person of the user..

OPINION

I discussed the principles underlying the exemption for sales of prescription medicines in my previous letter, so, for the sake of brevity will not repeat them here.

Words in a regulation are to be given their ordinary and plain meaning unless the context or apparent scope of the statute shows use in a technical or arbitrary sense. (People v. Eddy (1872) 43 Cal. 331, 336-337.) Webster's New World Dictionary defines “prosthesis” as “an artificial substitute for a missing part of the body.” You note in your letter that stutterers have perfectly normal ears, lungs, larynxes, jaws, lips. etc. Thus, the Biofeedback system does not replace any organ of the body. It also does not assist in the production of vocal utterances by the larynx. Rather, it administers therapy to the stutterer to help develop normal speech patterns leading eventually to independence from the System. As I noted in my previous letter, we have, for these reasons, previously determined that speech or communication aids are not prosthetic devices within the meaning of Regulation 1591(b) (4). As a result, we confirm our previous opinion that X-----’s sales of the Biofeedback System are subject to tax.

I hope the above discussion has answered your question. If you need anything further, please do not hesitate to write again.

Sincerely,

John L. Waid
Tax Counsel

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