August 21, 2002

Equipment Authorization Branch
Laboratory Division
Office of Engineering and Technology
Federal Communications Commission
7435 Oakland Mills Road
Columbia, MD 21046

Gentlemen:

Pursuant to Section 2.925(e) of the Federal Communications Commission's ("FCC's") rules, we are writing to request that the FCC approve an alternate method of labeling equipment subject to the equipment certification process. Data Sciences International, Inc. ("DSI") is preparing an application for certification of a series of low powered transmitters under Part 15 of the rules. Because the transmitters are for use only as devices implanted into laboratory research animals, we request that the FCC name plate (with the FCC identification number) be included in the accompanying user manual rather than on the device itself. Tania Hanna of Dorsey & Whitney LLP spoke with the Lab concerning this matter and you asked that we follow up with a written request memorializing our proposal.

Background

The series of devices that is the subject of this request is for use in monitoring blood pressure, temperature and other vital signs from laboratory animals used in biomedical research. This equipment is for use by pharmaceutical companies, government and military laboratories, toxicology testing labs and academic institutions. Implantable biomedical telemetry transmitters of the sort to be covered by our equipment authorization applications provide the most humane means available for collecting data from laboratory animals and can reduce the use of laboratory animals due to the elimination of stress and infections that are inherent with conventional techniques. As such, this type of equipment plays a vital role in biomedical research, helping pharmaceutical companies bring new drugs to market faster and providing the only means for researchers to conduct certain studies that advance medicine while helping society meet its goals for humane use and treatment of laboratory animals.

The devices in question are implantable radio-transmitters that emit a 455 kHz magnetic field that can be received up to seven feet from the animal. Since the emission is a near-field magnetic field, it

attenuates roughly as the distance from the antenna cubed. The maximum total battery power consumed by the devices is 750 uwatts. These devices are for use only in the research laboratory environment and are not intended for home use.

Request

Section 2.925(e) of the rules provides that

"where it is shown that a permanently affixed nameplate is not desirable or is not feasible, an alternative method of positively identifying the equipment may be used if approved by the Commission. The proposed alternative method of identification and the justification for its use must be included with the application for equipment authorization. NOTE: As an example, a device intended to be implanted within the body of a test animal or person would probably require an alternate method of identification."[1]

We understand that the name plate referenced in Section 2.925(e) lists the following information: 1) the FCC identifier and 2) other labeling requirements imposed by the rules. As discussed below, DSI requests that it be allowed to place the name plate referenced in Section 2.925 in the user manual. We submit that this would be an approach preferable to attempting to place the label on the outside of the device as implanted for the following reasons:

1. Because the device is to be implanted, the materials exposed to tissue must be biocompatible. This severely limits the options for labeling. There is no known biocompatible marking material that could be applied to the outside of the device once it has been manufactured.

2. Any information to be displayed on the device must be applied prior to encapsulating the device with a translucent biocompatible material. The area on the device available for labeling is small, whereas the lettering must be large enough to be readable through the distortion of the translucent biocompatible material. Thus, there is barely room for labeling the product with a readable manufacturer name, model and serial number. This latter information is required in recycling and in the identification of a transmitter that has been associated with a particular animal, once the transmitter has been removed from service. Accordingly, it is simply infeasible to imprint the FCC identifier and other required labeling information on the device itself.

3. Even though we might conceivably place the label or a portion of it inside the encapsulated biocompatible material, that label would become inaccessible and unreadable as soon as the transmitter is implanted. In addition, the labeling on the device would usually not be readable when in the sterile pouch. Therefore, the only time when an FCC identifier placed on the device would be readable would be during the few minutes of the surgical implant procedure between when the device has been removed from the sterile pouch and it is surgically placed in the animal.

All of the implantable transmitters to be covered by our application will be shipped in a sterile pouch which has a sticky-backed calibration label attached including serial number, model number, and

[1] 47 C.F.R. § 2.925(e).

calibrations for the transmitter. In order to avoid infection, the device must be kept in the sterile pouch until the time of surgery. At the time of surgery, the customer is instructed to peel the label from the sterile pouch and keep it in a safe place as long as the transmitter is in their possession. This is necessary because the calibrations on the label are required to interpret the data from the transmitter.

I urge you to consider favorably our request in light of the information we have presented above.

Sincerely yours,

DATA SCIENCES INTERNATIONAL

Perry A. Mills
Vice President and
Chief Technology Officer