SUPPLEMENTAL POLICIES

REGULATION OF FISH IDENTIFICATION PRODUCTS

Background:

Animal identification products are used in the aquaculture industry to identify fish for various management purposes. A small number of identification products, e.g., marking agents, have been reviewed by CVM. One, a medicated feed containing oxytetracycline, is approved for marking the skeletal tissue of Pacific salmon.

Position:

There are two basic categories of identification products used in fish. The first includes articles such as implanted electronic identification devices (EIDs) and coded identification tags. Such devices may be implanted subcutaneously (e.g., snout implants), clipped onto the surface of the animal (e.g., fin or operculum clips), or inserted into the musculature of the fish with the coded tag external to the body (spaghetti tags). Similar to such identification devices used in cattle, these are considered devices under Section 201(h) of the Federal Food, Drug, and Cosmetic Act (FFDCA) since they are intended to affect the structure of the animal and do not achieve their principal intended purpose through chemical action within or on the body of the animal. These devices are also considered food additives under Section 201(s) if they are implanted in edible tissue of fish and may reasonably be expected to become a part of food, either for animals or humans. Veterinary medical devices do not require premarket approval. However, identification products that meet the definition of food additives and are regulated as such, are subject to premarket review by FDA under Section 409 of the FFDCA.

The second category of identification products used in fish involves the use of substances that are administered orally (feed), or by immersion or injection, and chemically interact with the tissue of the fish. These substances are considered drugs under Section 201(g)(l)(C) since they are intended to affect the structure of the body of fish and achieve their intended purpose through chemical interaction within or on the body of the fish. Oxytetracycline and strontium, for example, are incorporated into the skeletal tissue of the animal, and can be detected by fluorescent or electron microscopy. Dyes, such as India ink, or paints that are administered intradermally are absorbed or bound by the dermal and/or epidermal tissues and can be detected visually. These substances would also be considered new animal drugs under Section 201(v) if labeled for use as identification, or marking agents, and as such, would be subject to the requirements of Section 512 of the FFDCA.

Although agents such as injectable dyes could also, by definition, be regarded as food or color additives when administered to food species of fish, we believe they are more appropriately regulated as drugs when used for identification purposes. Regulating these substances as drugs and new animal drugs, when labeled for use as identification or marking agents, provides premarket approval authority by CVM, which includes an evaluation of target animal safety, as well as human food and environmental safety.

Summary:

Fish Identification Products will be classified as follows:

I. Devices (achieve intended purpose without chemical interaction)

A. Implants

Example: electronic identification devices (EIDs), e.g., snout implants

Note: Devices implanted in edible tissue are also considered food additives.

B. External tags

Example: fin and operculum clips, spaghetti tags

II. Drugs (achieve intended purpose through chemical interaction)

A. Orally administered products

Example: oxytetracycline medicated feed

B. Immersion administered products

Example: oxytetracycline, strontium - bath or dip

C. Injectable products

1. Systemic effect

Example: injectable oxytetracycline

2. Local effect

   Example: India ink, acrylic paints, other dyes