Date of Index Listing: March 4, 2026

FREEDOM OF INFORMATION (FOI) SUMMARY

ORIGINAL REQUEST FOR ADDITION TO THE INDEX OF LEGALLY MARKETED UNAPPROVED NEW ANIMAL DRUGS FOR MINOR SPECIES

MIF 900-054

Prazi-Med™

(praziquantel powder for immersion)

Ornamental finfish (except *Callichthyidae* and *Cleridae* catfish)

Requested by:

Aqion, LLC

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I. GENERAL INFORMATION

A. File Number

MIF 900-054

B. Requestor

Aqion, LLC
539 W. Commerce Street
Suite 6825
Dallas, Texas 75208

C. Proprietary Name

Prazi-Med™

D. Drug Product Established Name

praziquantel powder for immersion

E. Pharmacological Category

Antiparasitic

F. Dosage Form

Powder

G. Amount of Active Ingredient

99.5% w/w praziquantel

H. How Supplied

50 g and 250 g PET bottles, 10 g mylar packet

I. Dispensing Status

Over the Counter (OTC)

J. Dosage Regimen

10.2 milligrams of Prazi-Med™ per gallon of aquarium water for 2 doses (Day 1 and Day 8)

K. Route of Administration

Immersion

L. Species/Class

Ornamental finfish except *Callichthyidae* and *Cleridae* catfish

M. Indication

For the treatment of internal parasites (flukes and tapeworms) and external parasites (flukes) susceptible to praziquantel in ornamental finfish, except *Callichthyidae* and *Cleridae* catfish.

II. EFFECTIVENESS AND TARGET ANIMAL SAFETY

In accordance with 21 CFR part 516, a qualified expert panel evaluated the target animal safety and effectiveness of Prazi-Med™ powder for immersion for the treatment of internal parasites (flukes and tapeworms) and external parasites (flukes) in ornamental finfish (except Callichthyidae and Cleridae catfish) and determined whether the benefits of using Prazi-Med™ for the proposed use outweigh its risks to the target animals. FDA found the below qualified expert panel members acceptable as per 21 CFR 516.141(b). The members of the qualified expert panel were:

- Roy P. E. Yanong, VMD - Panel Leader
- Natalie Stillwell, PhD
- Nicholas Saint-Erne, DVM

A. Findings of the Qualified Expert Panel

The qualified expert panel (the panel) performed a comprehensive review of available literature, scientific publications, fish medicine textbooks, and information over the last 40 years involving the safety and effectiveness of praziquantel, the active ingredient in Prazi-Med™. In addition to the literature review, the panel used both anecdotal experience and their own expertise in fish health to complete their assessment of the target animal safety and effectiveness of Prazi-Med™ in ornamental finfish.

The panel stated in their report that praziquantel has a long-standing history of being used as an immersion treatment for a variety of freshwater and marine species within the food, sport, and ornamental fish industries. Aquatic veterinary textbooks and drug dosage guides since 1988 have consistently recommended praziquantel at dosages ranging from 1-20 mg/L for durations of 1-48 hours, which are currently being used by practicing aquatic veterinarians. The panel also conducted a comprehensive review of 37 peer-reviewed articles published between 1987 and 2020 involving the effectiveness of the active ingredient found in Prazi-Med™ used as an immersion to control flatworm parasites in fish hosts. The majority of studies summarized in these articles reported that praziquantel was at least 80% effective, while 27 out of 37 studies showed between 90% and 100% effectiveness when controlling parasites. Six studies reported less than 80% effectiveness of praziquantel, but the panel concluded that rates of effectiveness could have been improved with longer duration of treatment and appropriate dosing.

The panel used this information in addition to their own experience using praziquantel to support dosing recommendations for Prazi-Med™. One study reviewed by the panel (Zuskova, 2018) evaluated effectiveness and safety of praziquantel in barbel (*Barbus barbus L.*) that were naturally infected with helminths. The fish were tested for acute toxicity with either 5, 10, 20, 30, or 40 mg/L of praziquantel. The acute toxicity showed dosing with 30-40 mg/L caused respiratory distress, loss of reflexes, and irregular movement. They noted that at 96 hours of treatment, there was a 0% mortality at 20.2

mg/L, 50% mortality of 28.6 mg/L, and 100% mortality at 40.6 mg/L. Clinical signs did resolve after fish were removed from treatment. Based on these results, they treated fish to a bath treatment with praziquantel at 10 mg/L or 20 mg/L for 96 hours and both were 100% effective against the parasites. This study demonstrated that acute toxicity could occur at higher levels of praziquantel even at short treatment intervals. Therefore, the panel supports the recommended dose of Prazi-Med™, which is lower than what was shown to be safe in this study.

In addition, the panel reviewed 9 articles involving target animal safety associated with the use of praziquantel in finfish species. LC_{50} concentrations (to determine fish safety) ranged from 13.4 mg/L in African catfish (*Clarias gariepinus*) to 63.4 mg/L in golden shiner (*Notemigonus crysoleucas*), with additional values of 55.1 mg/L in grass carp and 39.9 mg/L in zebrafish (*Danio rerio*). One study reported that treating European eel (*Anuilla anguilla*) with praziquantel at doses ranging between 600-1200 mg/L caused paralysis within 60 seconds whereas a dose of 120 mg/L caused paralysis within 18 minutes. The panel concluded that the studies they reviewed generally indicate a high margin of safety associated with the administration of praziquantel via immersion. However, studies showed that adverse events may still occur, especially at higher doses. Fish may exhibit loss of normal orientation and/or buoyancy, erratic swimming, respiratory distress, paralysis, hyperactivity or lethargy, and in some cases, death can also occur. The panel also noted in their report that some members of the *Cleridae* and *Callichthyidae* families of catfish may have a higher sensitivity to praziquantel. One study (Obiekezie & Okafor, 1995) revealed 50% mortality in African Sharptooth Catfish (*Clarias gariepinus*) when treated with as low as 13.4 mg/L of praziquantel. Another study (Nwani, 2014) conducted in African Sharptooth Catfish (*Clarias gariepinus*) showed 10%, 50%, and 100% mortality rates following doses of 35 mg/L, 53.52 mg/L, and 60 mg/L, respectively, after 96 hours of exposure to praziquantel. Due to a lack of information available on dosing for catfish with sensitivities, the panel recommended that praziquantel not be used in members of the *Cleridae* and *Callichthyidae* families of catfish.

Based on their thorough review of the literature, anecdotal information, and expert opinion, the qualified expert panel unanimously concluded that the benefits of using Prazi-Med™ for the treatment of internal parasites (flukes and tapeworms) and external parasites (flukes) susceptible to praziquantel in ornamental finfish, except *Callichthyidae* and *Cleridae* catfish, outweigh the risks to the target animals. The panel also recommended that Prazi-Med™ should be made available over the counter (OTC).

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III. USER SAFETY

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to Prazi-Med™:

USER SAFETY WARNINGS:
Not for use in humans. Keep out of reach of children.

Use in well-ventilated area and avoid inhalation.

Avoid dust formation. Wear eye protection, dust mask, and chemical-resistant gloves when handling the drug.

Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling, and before eating, drinking, chewing gum, using tobacco products, or using the toilet.

If inhaled and breathing becomes difficult, move victim to fresh air. Seek medical attention.

If ingested: If the person is conscious, rinse mouth out with water and then drink plenty of water. Seek medical attention.

If in eyes: Rinse eye immediately with water for at least 15 minutes. If symptoms occur, seek medical attention.

Wash skin with soap and water, and launder clothing with detergent. If symptoms occur, seek medical attention.

IV. AGENCY CONCLUSIONS

The information submitted in support of this request for Prazi-Med™ to be added to the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species (Index) for the treatment of internal parasites (flukes and tapeworms) and external parasites (flukes) susceptible to praziquantel in ornamental finfish, except *Callichthyidae* and *Cleridae* catfish satisfies the requirements of section 572 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and 21 CFR part 516.

A. Determination of Eligibility for Indexing

As part of the determination of eligibility for inclusion in the Index, FDA determined that the drug for this intended use in ornamental finfish, except *Callichthyidae* and *Cleridae* catfish was safe to the user, did not individually or cumulatively have a significant effect on the human environment, and that the description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packaging of the new animal drug was sufficient to demonstrate that the requestor has established appropriate specifications for the manufacture of the new animal drug. Additionally, the requestor has committed to manufacture the drug in accordance with current good manufacturing practices (CGMP).

The Index is only available for new animal drugs intended for use in minor species for which there is a reasonable certainty that the animal or edible products from the animal will not be consumed by humans or food-producing animals and for new animal drugs intended for use only in a hatchery, tank, pond, or other similar contained man-made structure in an early, non-food life stage of a food-producing minor species, where safety for humans is demonstrated in accordance with the standard of section 512(d) of the act. Because this new animal drug is not intended for use in food-

producing animals, FDA did not require data pertaining to drug residues in food (i.e., human food safety) for granting this request to for addition to the index listing.

B. Qualified Expert Panel

The qualified expert panel for Prazi-Med™ met the selection criteria listed in 21 CFR 516.141(b). The panel satisfactorily completed its responsibilities in accordance with 21 CFR part 516 in determining the target animal safety and effectiveness of Prazi-Med™ for use for the treatment of internal parasites (flukes and tapeworms) and external parasites (flukes) susceptible to praziquantel in ornamental finfish, except *Callichthyidae* and *Cleridae* catfish.

C. Marketing Status

The qualified expert panel recommended that Prazi-Med™ be available as an over-the-counter (OTC) product for this intended use. The Agency agrees that this product can be marketed OTC because the product labeling contains adequate directions for use by laypersons and the conditions of use prescribed on the label are reasonably certain to be followed in practice.

D. Exclusivity

Products listed in the Index do not qualify for exclusive marketing rights.