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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

June 4, 2012

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Ms. Julie Ownbey, Regulatory Affairs Manager
Clearon Corporation
95 MacCorkie Avenue, S.W.
South Charleston, WV 25303

Subject: Notification per PR Notice 98-10
Product: **Inovotabs**
EPA Registration Number: **71847-3**
Application Date: May 11, 2012
Application Receipt: May 14, 2012

Dear Ms. Ownbey:

This acknowledges receipt of the above notification application, submitted under the provision of PR Notice 98-10, FIFRA 3(c) 9.

Proposed Notification:

Medentech, Ltd. has submitted a Minor Label Change for the Invotabs Master Label, **EPA Reg. No. 71847-3**. The modifications to this label are consistent with the provisions of PR Notice 98-10.

These modifications include removing Pfizer's name from the label, additional words that add clarification to the directions for use and adding Medentec's email address to the label.

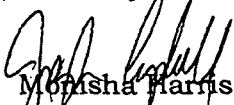
General Comments:

Based on a review of the material submitted, the following comment applies.

The Notification application is **acceptable**. A copy of the **accepted** Notification has been inserted in your file for future reference.

If you have any questions or comments concerning this letter, please contact Killian Swift via email at swift.killian@epa.gov or by telephone at 703-308-6346 during the hours of 5:00 AM to 12:00 PM EDT.

Sincerely,



Monisha Harris,
Product Manager 32
Regulatory Management Branch II
Antimicrobials Division (7510P)

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PREPARATION FOR MIXING INOVOTABS®

- Add 2 INOVOTABS® tablets to 1 gallon of warm water 75°F-104°F (23°C-40°C). Lower temperatures will extend dissolution time of the tablets.
- If hatchery water supply is below 64°F (18°C) take measures to ensure water temperature is within an acceptable range at mixing time. This can include storing water overnight so that it rises to room temperature. It is important that the water temperature be raised to at least room temperature; 68°F-77°F (20°C-25°C). It is also critical that water temperature stay at or below 104°F (40°C) as temperatures higher than 104°F may reduce solution efficiency.
- [Higher] Temperatures over 120°F (50°C) can cause release of chlorine to the air and thus reduce chlorine concentration of the sanitizer solution.
- Tablets should be completely dissolved before use.
- Inovotabs® solution must be freshly prepared.
- Use within one day.
- Keep in a properly labeled [batch] container to protect against contamination.
- Unused solution should be discarded in accordance with Pesticide Disposal directions on label.
- Inovotabs® must be mixed to yield solution that has a minimum concentration of 2221 ppm of [free] chlorine. This is achieved by dissolving two (2) Inovotabs® per gallon of water.

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STEP BY STEP INOVOTABS® MIXING DIRECTIONS:

- 1) Rinse out all containers and clean before daily use
- 2) Use drinking or potable tap water to make the Inovotabs® solution and prepare in an ~~Pfizer Embrex Inovoject® system~~ approved [batch] container.
- 3) Add 2 tablets per gallon (1 tablet per 2 liters of water).
- 4) Warm water 75°F-104°F (23°C-40°C) may be used. **DO NOT BOIL**
- 5) Allow tablets to dissolve completely, then [stir] agitate carefully prior to use.
- 6) Be sure the solution is not hot when the ~~Embrex Inovoject® system~~ is injecting eggs.
- 7) Connect the container with freshly prepared Inovotabs® solution to the Inovoject® sanitation and cleaning system by carefully placing the collection tubes in the sanitizer solution and tightening the lid.
- 8) During normal operation additional sanitizer solution may be required. To add additional fluid to the needle punch sanitation system stop the ~~Pfizer Embrex Inovoject® system~~, remove the sanitizer container and prepare a new batch of Inovotabs® solution or refill the current sanitizer container in place via a secondary [batch] container that was previously prepared with Inovotabs® solution.
- 9) Make a fresh solution at the start of each injection day.
- 10) Follow all appropriate safety guidelines when handling tablets.
- 11) Twist close plastic bag and close lid firmly after withdrawing tablets from container.

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