US Environmental Protection Agency Office of Pesticide Programs

Thyme Herbs and Ground Sesame Plant – Final Work Plan Registration Review - Case 6060

May 29, 2008

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Approved by: _____

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Introduction:

The Agency is implementing the new Registration Review program and plans to review each registered pesticide every 15 years to determine whether it continues to meet the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) standard for registration. Changes in science, public policy, and pesticide use practices will occur over time. The registration review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered products continue to meet that statutory standard. The public phase of registration review begins when the initial docket is opened for each case. Information on this program is provided at http://www.epa.gov/oppsrrd1/registration review/.

This is EPA's ***Final Work Plan*** for the registration review case 6060: thyme herbs and ground sesame plant. The registrant (Aquarium Pharmaceuticals, Inc.) of the last registered product (EPA Reg. No. 8709-7) containing the active ingredient, thyme herbs, received a) a late-December 2004 invoice requiring payment by January 15, 2005, of the 2005 maintenance fee, b) a mid-February 2005 Notice of Intent to Cancel, and c) a July 21, 2005 Cancellation Order. The Agency informed the public of the product's cancellation for non-payment of the 2005 maintenance fee in a *Federal Register* notice which was published on August 3, 2005 (70 FR 44637). The registrant (Sesaco Corporation) of the last registered product (EPA Reg. No. 58246-1) containing the active ingredient, ground sesame plant, received a) a late-December 2005 invoice requiring payment by January 15, 2006, of the 2006 maintenance fee, b) a mid-February 2006 Notice of Intent to Cancel, and c) a July 18, 2006 Cancellation Order. The Agency informed the public of the product's cancellation for non-payment of the 2006 maintenance fee in a *Federal Register* notice which was published on August 2, 2006 (71 FR 43748). Consequently, there are currently no active FIFRA section 3 or 24(c) registered pesticide products containing the registration review case 6060 active ingredients, thyme herbs or ground sesame plant.

However, when in accordance with all of the criteria of 40 CFR 152.25(f), products containing 'thyme,' 'thyme oil,' 'sesame (includes ground sesame plant)' or 'sesame oil' as the active ingredient are 'minimum risk pesticides,' exempt from the requirements of FIFRA (61 FR 8878; March 6, 1996).

Although there is not a tolerance or exemption from the requirement of a tolerance for the specific active ingredient thyme herbs, the tolerance exemptions for 'minimal risk active and inert ingredients' under 40 CFR 180.950(a)(1)(ii) and (iii) (67 FR 36534; May 24, 2002), for residues of spices and herbs, respectively, are applicable to thyme herbs and provide the necessary Federal Food, Drug, and Cosmetics Act coverage for food uses of any 40 CFR 152.25(f)-compliant thyme or thyme oil product(s). Because the tolerance exemptions under 40 CFR 180.950 were established in 2002, it has been determined that they meet the safety standards of the FFDCA, as amended by the FQPA of 1996.

Furthermore, although there is not a tolerance or exemption from the requirement of a tolerance for the specific active ingredient ground sesame plant, the tolerance exemption under 40 CFR 180.1087 (53 FR 5379; February 24, 1988), for residues of the nematicide sesame stalks, is applicable to ground sesame plant and provides the necessary FFDCA coverage for certain food uses of any 40 CFR 152.25(f)-compliant ground sesame plant nematicide product(s). The tolerance exemption under 40 CFR 180.1087 authorizes nematicidal applications to the following crops: cotton, soybeans, potatoes, sugarbeets, tomatoes, bell peppers, squash, strawberries, eggplants, cucumbers, carrots, radish, turnips, onions, peas, melons, grapes, walnuts, almond, orange, grapefruit, mulberry, peach, apple, apricot, blackberry, loganberry, pecan, cherry, plum, and cranberry. As required by the FQPA of 1996, a tolerance reassessment for 'ground sesame stalk' was completed on May 14, 2002 (Tolerance Reassessment Decision; J. L. Andersen to L. Rossi). The Agency concluded that the health effects database supporting the exemption from tolerance met the safety standards of the FFDCA, as amended by the FQPA of 1996. Although there are no active FIFRA section 3 or 24(c) registered products containing ground sesame plant as the active ingredient, the reassessed tolerance exemption under 40 CFR 180.1087 will be retained as it provides the necessary FFDCA coverage for specifically-listed food crop uses of any 40 CFR 152.25(f)-compliant ground sesame plant nematicide product(s).

Risk Assessment and Data Needs:

Due to the facts that there are neither FIFRA section 3 or 24(c) registered products containing thyme herbs as an active ingredient nor thyme herbs-specific tolerances or tolerance exemptions, and because the 'minimal risk active and inert ingredients' exemptions under 40 CFR 180.950 for spices and herbs (which provide FFDCA coverage of 40 CFR 152.25(f)-compliant thyme herbs products) was established in 2002 and so meets the safety standards of the FFDCA, as amended by the FQPA of 1996, further risk assessments and submission of data are not necessary.

Due to the facts that there are neither FIFRA section 3 or 24(c) registered products containing ground sesame plant as an active ingredient nor ground sesame plant-specific tolerances or tolerance exemptions, and because the sesame stalks tolerance exemption (which will be retained to provide FFDCA coverage, for certain food uses, of 40 CFR 152.25(f)-compliant ground sesame plant nematicide products) was successfully reassessed in 2002, further risk assessments and submission of data are not necessary.

Next Steps:

The ***Final Work Plan*** for thyme herbs and ground sesame plant will be posted on the Agency's website (http://www.epa.gov).