# 06/13/2006



#### U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs Registration Division (7505C) Ariel Rios Building 1200 Pennsylvania Ave., NW Washington, D.C. 20460 EPA Reg. Number: 71512-14

Date of Issuance:

JUN 13 2006

NOTICE OF PESTICIDE:

x Registration

\_\_\_ Reregistration (under FIFRA, as amended)

Term of Issuance: conditional

Name of Pesticide Product:

Flonicamid 50 WG for Manufacturing and Repackaging Use Only

Name and Address of Registrant (include ZIP Code):

Myron Bliss, Jr. Ph.D.

ISK Biosciences

7470 Auburn Road Suite A

Concord, Ohio 44077

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA Sec. 3(c)(A) and (B) provided that you submit acceptable data listed in attachment A and make the label changes listed below. Once a pesticide is registered, however, it is not regarded as permanently acceptable. Registration does not eliminate the need for continual reassessment of pesticides. If the Agency determines that, at any time, additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under FIFRA section (3)(c)(2)(B).

### Label changes:

- 1. Change the EPA Reg. No. to 71512-14.
- 2. Insert the signal word Warning under the statement Hazards to Humans and Domestic Animals.
- 3. Change the container disposal instructions for steel drums to read as follows: Steel Drum. Triple rinse (or equivalent). Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

Signature of Approving Official:

Date:

JUN 1 3 2006

Richard Gebken

Product Manager 10

Insecticide Branch

Registration Division (7505C)

EPA Form 8570-6

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Submit two copies of the revised final printed label for the record.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

# Attachment A

# Data Required as Condition of Registration

Data Requirement/Title/ Due Date	Comment
860.1300 Nature of the Residue – Livestock Due date: As specified in the Notice of Registration dated April 12, 2006.	The conditions and parameters used in the goat metabolism study should be provided: age of test animals; breed of test animals; storage temperature for samples and extracts; accountability of extraction procedures (un-normalized values for extractable and nonextractable residues); limit of detection for combu stion/LSC and HPLC analyses; HPLC raw data results (peak area or height counts) for extract analyses (except for the analysis of kidney extracts from Goat 1, which were provided as an example); the radioactivity remaining in the solids following acid and/or protease hydrolyses of tissue samples; confirmation of the identification of major metabolites (>10% TRR) in each livestock matrix; and the HPLC chromatograms from the final storage stability analyses.  The conditions and parameters used in the hen metabolism study should be provided: storage temperature for samples and extracts; accountability of extraction procedures (un-normalized values for extractable and nonextractable residues); limit of detection for combustion/LSC and HPLC analyses; HPLC raw data results (peak area or height counts) for extract analyses (except for the analysis of liver extracts, which were provided as an example); the radioactivity remaining in the solids following acid and/or protease hydrolyses of liver samples; metabolite identifications to be confirmed by a second method in each tissue in which the metabolite is found in significant quantities (310% TRR) and the HPLC chromatograms from the final analyses of hen matrices (for supporting storage stability).
860.1340 Residue Analytical Methods – Plants Due date: As specified in the Notice of Registration dated April 12, 2006.	Adequate method validation or concurrent recovery data (refer to Deficiencies 5b-d) at the method LOQ and at expected residue levels for the processed commodities of apple (wet pomace), dried plum, potato (chips and wet peel), and tomato (paste and puree) are required.  Adequate validation data at the stated method LOQ (0.02 ppm) is required for cotton gin byproducts.

Data Requirement/Title/ Due Date	Comment
	An explanation for the low recoveries of TFNA-AM and correspondingly high recoveries of TFNA in wheat straw in the radiovalidation study should be provided.
·	Method FMC-No. P-3561 as currently written only includes instructions for analysis of samples of peach, potato tuber, wheat straw, cotton matrices and potato chips. The method should be rewritten to include instructions for the analyses of all crops (and their associated processed commodities) for which petitioner is requesting tolerances.
860.1520 Processed Food and Feed Due date: As specified in the Notice of Registration dated April 12, 2006.	Concurrent processing validation data for potato processed commodities (potato tubers, wet peels, flakes, and chips) at the stated method LOQ and at the expected residue levels for each analyte in each commodity should be submitted. The reported limit of quantitation (LOQ) was 0.01 ppm and the limit of detection (LOD) was 0.005 ppm for each analyte in/on potato commodities. The lower limit of validation for each analyte was 0.2 ppm for potato flakes and tuber; no validation data were provided for potato wet peel or chips. EPA requires concurrent validation data at the LOQ and levels that approximate the concentrations in the potato processed commodities.  The apple processing study is invalid because concentration of residues in both wet apple pomace and juice is theoretically impossible. Averaging the residues found in the wet apple pomace and juice is not acceptable. The petitioner should conduct another processing study and submit concurrent validation data for apples, apple juice and wet pomace.  The petitioner should submit concurrent validation data for tomato fruit, paste, and puree at the stated method LOQ and at the expected residue levels for each analyte in each commodity.  Tomato: The tomato processing data indicate that the combined residues of flonicamid, TFNA-AM, TFNA, and TFNG appear to concentrate in puree (11.7x average processing factor) and paste (6.9x average processing factor). According to Table 2 of OPPTS 860.1520, the theoretical concentration factors, based on loss of water, are 1.4x for puree and 5.5x for paste. The results in the processing study where the processing factors exceed the theoretical concentration factors are irregular. Therefore, a concurrent method recovery data in tomato paste and puree are required to verify the results.

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FIRST AID		
If in Eyes	<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>	
If Swallowed	<ul> <li>Call a poison control center or doctor for treatment immediately for treatment advice.</li> <li>Have person sip a glass of water if able to swallow.</li> <li>Do not induce vomiting unless told to do so by the poison control center or doctor.</li> <li>Do not give anything by mouth to an unconscious person.</li> </ul>	
If Inhaled	<ul> <li>Move person to fresh air.</li> <li>If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li> <li>Call a poison control center or doctor for further treatment advice.</li> </ul>	
If on Skin or Clothing	<ul> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>	
	<b>lical Doctor:</b> Treatment is controlled by removal of e followed by symptomatic and supportive care.	
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Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

#### HOT LINE NUMBER

For 24-Hour Medical Emergency Assistance call 1-888-484-7546. For Chemical Emergency, Spill, Leak, Fire or Accident, call CHEMTREC 1-800-424-9300.



JUN 1 3 2001

FLONICAMID 50WG

ancended, for the pesticide REPACKAGING USE ONLY

ACTIVE INGREDIENT:	By Wt.
*Flonicamid	50.0%
INERT INGREDIENTS	50.0%
Total	
*Contains 0.5 pounds active ingredient per pound of formulated produc	et
U.S. Patent No. 5360806	

# KEEP OUT OF REACH OF CHILDREN

# WARNING

## **AVISO**

Si usted no entiende la etiqueta, busque a alquien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

See side panel for additional precautionary statements.

Read entire label carefully and use only as directed.

**ISK Biosciences Corporation** 

7470 Auburn Road, Suite A Concord, Ohio 44077 U.S.A.

EPA Reg. No. 71512-

EPA Est. No. 69029-ITA-001

Made in Japan

Net Contents: 176 pounds (80 kilograms)



#### **PRECAUTIONARY STATEMENTS**

#### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Causes substantial but temporary eye injury. Harmful if swallowed or absorbed through skin. Avoid contact with skin. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses). Avoid breathing dust or spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove contaminated clothing and wash clothing before reuse.

#### **ENVIRONMENTAL HAZARDS**

DO NOT discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

# THIS PRODUCT IS FOR MANUFACTURING AND REPACKAGING USE ONLY.

Only for formulation or repackaging into insecticides for use in commercial greenhouses, interior plantscapes, nursery and landscape ornamentals, cotton, cucurbit vegetables, fruiting vegetables and leafy vegetables (except Brassica), potato, pome fruit and stone fruit. This product may be used to formulate products for any additional uses not listed on this label if the formulator, user group, or grower has complied with USEPA data submission requirements regarding support of such uses.

# STORAGE AND DISPOSAL

DO NOT contaminate water, food or feed by storage or disposal. Open dumping is prohibited.

STORAGE: Store in original container, in a secured, dry and cool place separate from other pesticides, fertilizer, food, and feed.

PESTICIDE DISPOSAL: Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: DO NOT reuse empty plastic bags. Completely empty plastic bags into formulation or repackaging equipment by shaking and tapping sides and bottom of the bags to loosen clinging particles. Then dispose of plastic bags in a sanitary landfill or by incineration if allowed by state and local authorities. If burned, stay out of smoke. If the steel drum is contaminated and cannot be reused, offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill or by other procedures approved by state and local authorities.

#### WARRANTY AND LIMITATION OF DAMAGES

Seller warrants to those persons lawfully acquiring title to this product that at the time of first sale of this product by Seller that this product conformed to its chemical description and was reasonably fit for the purposes stated on the label when used in accordance with Seller's directions under normal conditions of use, and Buyers and users of this product assume the risk of any use contrary to such directions. EXCEPT AS PROVIDED ELSEWHERE IN WRITING CONTAINING AN EXPRESS REFERENCE TO THIS WARRANTY AND LIMITATION OF DAMAGES, SELLER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OR GUARANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR OF MERCHANTABILITY, AND NO AGENT OF SELLER IS AUTHORIZED TO DO SO. In no event shall Seller's liability for any breach of warranty or guaranty exceed the purchase price of the product as to which a claim is made. Buyers and users of this product are responsible for all loss or damage from use or handling of this product which results from conditions beyond the control of Seller, including, but not limited to, incompatibility with other products unless otherwise expressly provided in Directions for Use of this product, weather conditions, cultural practices, moisture conditions or other environmental conditions outside of the ranges that are generally recognized as being conducive to good agricultural and/or horticultural practices.

