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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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FEB 27 1998

Dr. Demetra Vlachos  
Senior Manager, Biotechnology Regulatory Affairs  
Novartis Seeds, Inc. - Field Crops - NAFTA  
P.O. Box 12257  
Research Triangle Park, NC 27709-2257

Dear Dr. Vlachos:

Subject: Label Amendment Application to Amend the Term and Condition of the Subject  
Registration to Allow Unlimited Use Of Bt11 Bt Corn in Ten Counties of the Texas  
Panhandle  
EPA Registration No. 67979-1

The amendment referred to above, submitted in connection with registration under the Federal  
Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the following  
comments.

1) The term and condition restricting commercial sale listed in item 11 of our 1/24/97  
letter approving limited use in the South is modified to read as follows:

Novartis will ensure that in the combined states of Alabama, Arkansas, Georgia, Florida, Louisiana, North  
Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Bryan, Caddo, Canadian, Garvin,  
and Grady), Tennessee (only the counties of Carroll, Chester, Crockett, Fayette, Franklin, Gibson,  
Hardeman, Hardin, Haywood, Henderson, Lake, Lauderdale, Lawrence, Lincoln, McNairy, Madison,  
Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley,  
Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of  
Greensville, Isle of Wight, Northampton, Southampton, Sussex, Suffolk) and Missouri (only the counties of  
Butler, Dunklin, Mississippi, New Madrid, Pemiscot, Scott, Stoddard) that the combined sale of this plant-  
pesticide in all the above states will not exceed the amounts required to plant 100,000 acres per anum.  
Further, Novartis will ensure that for the states and counties listed above that the amount sold will result in  
no more than 5% of the corn planted in any county with more than 1000 acres of cotton. Per item 8 of the  
1/24/97 letter Novartis will report all sales of this product by Novartis or its distributors annually to EPA no  
later than January 31st of the following year.

2) Correct the name and address of Novartis Seeds, Inc. on the label to reflect Novartis  
Seeds, Inc. - Field Crops - NAFTA.

CONCURRENCES

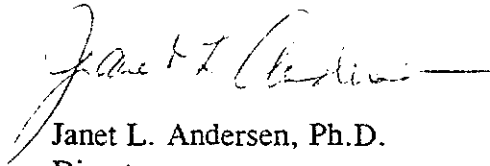
SYMBOL	7511W	7511W					
SURNAME	<i>[Signature]</i>	<i>[Signature]</i>					
DATE	2/26/98	2/27/98					

2/4

A stamped copy of the label is enclosed for your records. Submit five (5) copies of the final printed labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of Bt corn into commerce with the amended grower guide constitutes acceptance of these conditions.

Sincerely,



Janet L. Andersen, Ph.D.  
Director  
Biopesticides and Pollution  
Prevention Division (7511W)

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

3/4

# INSECT RESISTANT CORN

## Bt Protein Plant Pesticide Active Ingredient for the Control of European Corn Borer in Corn

(Pure form of the plant pesticide,  
*Bacillus thuringiensis* subsp. *kurstaki* delta-endotoxin protein,  
as expressed in corn cells)

### Active Ingredient:

*Bacillus thuringiensis* CryIA(b) delta-endotoxin  
and the genetic material (plasmid vector  
pZO1502) necessary for its production  
in corn ..... 0.0002 - 0.0006%  
by seed weight

### Inert Ingredient:

Substance produced by a marker gene and its  
controlling sequences in corn ..... < 0.0000001%  
by seed weight

Keep Out of the Reach of Children

### CAUTION

Keep out of lakes, ponds or streams. Do not contaminate water  
by cleaning of equipment or disposal of wastes.

**ACCEPTED**  
**with COMMENTS**  
**In EPA Letter Dated**

FEB 27 1998

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
as amended, for the pesticide  
registered under EPA Reg. No.  
67979-1

EPA Reg. No. 67979-1  
EPA Est. No. 67979-IA-2

Novartis Seeds, Inc.  
7500 Olson Memorial Highway  
Golden Valley, MN 55427

