

Citizens' Oversight Projects (COPs)

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El Cajon, CA 92019
CitizensOversight.org
619-447-3246

June 26, 2015



TO: FDA
RE: FOIA Request

SUBJECT: Records related to BNF0035

Dear Representative:

We hereby submit this Freedom of Information Act Request. Please provide all material in electronic form if possible. Please provide a link to online information if that is available.

Regarding file designation BNF0035

(<http://www.accessdata.fda.gov/scripts/fdcc/index.cfm?set=Biocon&id=MON-80200-7>)

Here is the data record on that web page:

Submission Date:	Jul 2, 1996
Developer Name:	Monsanto Company
Developer Contact Information:	800 N. Lindbergh Boulevard, St. Louis, MO 63167
Intended Use:	For use in human food and animal feed
Trait 1 Added Protein or DNA:	CryIAb
Source:	<i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> (Btk)
Intended Effect:	Resistance to European corn borer;
Trait 2 Added Protein or DNA:	5-Enolpyruvylshikimate-3-phosphate synthase (EPSPS)
Source:	<i>Agrobacterium</i> sp. strain CP4
Intended Effect:	Tolerance to the herbicide glyphosate
Trait 3 Added Protein or DNA:	Glyphosate oxidoreductase
Source:	<i>Ochrobactrum anthropi</i>
Intended Effect:	Tolerance to the herbicide glyphosate
Requires EPA Review?*	Yes
Event Designation:	MON 802
Unique Identifier code:	MON-80200-7
FDA Letter Date	Nov 5, 1996
FDA Memo Date	Sep 6, 1996

Please provide:

1. Regarding the following quote from the Sept 6, 1996 FDA Memo mentioned above:
“In a submission dated July 2, 1996, Monsanto Company provided summary information to support their safety and nutritional assessment of new corn lines MON 802, 805, 830, 831 and 832.”
--> Please provide the “submission of July 2, 1996”

2. Based on the quote from Nov 5, 1996 FDA Memo mentioned above:
 1. Quote: “On March 10, 1995, Monsanto met with FDA to discuss the proposed safety and nutritional assessment of corn containing transformation events that confer pesticidal activity and herbicide tolerance.”
--> Please provide meeting notes and any other records related to the meeting that occurred on March 10, 1995.
 2. Quote: “These communications informed FDA of the steps taken by Monsanto to ensure that these products comply with the legal and regulatory requirements that fall within FDA's jurisdiction.”
--> Please include records defining the “steps taken by Monsanto.”
 3. Quote: “Based on the safety and nutritional assessments you have conducted, it is our understanding that Monsanto has concluded that corn grain (kernels), fodder and silage derived from the new varieties are not materially different in composition, safety, and other relevant parameters from corn grain (kernels), fodder and silage currently on the market, and that the genetically modified corn does not raise issues that would require premarket review or approval by FDA.”
--> Please provide the safety and nutritional assessments conducted by Monsanto, in either exhaustive or summary form, as reviewed by FDA staff to reach its “understanding.”
 4. Quote: “All materials relevant to this notification have been placed in a file designated BNF0035. This file will be maintained in the Office of Premarket Approval.”
--> Please provide all other information in the file designated BNF0035
 5. Quote: “Based on the information Monsanto has presented.”
--> Please provide all the information presented by Monsanto, any questions your staff had about that information, and any followup responses by Monsanto.
 6. Quote: “However, as you are aware, it is Monsanto's responsibility to ensure that foods marketed by the firm are safe, wholesome and in compliance with all applicable legal and regulatory requirements.”
--> Please provide documents that define “safe” and “wholesome”
--> Please provide documents that define “all applicable legal and regulatory requirements” which are maintained by your agency related to such genetically engineered food such as MON802

3. Please provide meeting notes and any other records related to any other meetings on BNF0035 other than the March 10, 1995 meeting, as mentioned above.

Thank you for your kind assistance,
Sincerely,



Raymond Lutz
National Coordinator, Citizens' Oversight Projects