

Exhibit

5



Technical Products Division

P.O. Box 219  
Highland, IL 62249-0219  
(618) 654-2070  
(800) 641-2001  
Fax: (618) 654-1105

June 30, 1995

DuCoa L.P.  
Technical Products Division  
P. O. Box 219  
Highland, IL 62249  
June 30, 1995

Natamycin as a mold retardant of *Aspergillus parasiticus*, *Penicillium rubrum*, and *Fusarium moniliforme* for up to 14 days in broiler chicken feed at a level of 11 ppm

Food and Drug Administration  
CENTER FOR VETERINARY MEDICINE  
Director, Division of Animal Feeds (HFV-220)  
7500 Standish Place  
Rockville, MD 20855

Dear Sirs:

The undersigned, DuCoa L.P. submits this petition pursuant to section 409(b)(1) of the Federal Food, Drug, and Cosmetic Act with respect to natamycin as a mold retardant of *Aspergillus parasiticus*, *Penicillium rubrum*, and *Fusarium moniliforme* for up to 14 days in broiler chicken feed at a level of 11 ppm.

Attached hereto, in triplicate, and constituting a part of this petition, are the following:

- A. Identity
- B. Use
- C. Intended Technical Effect
- D. Analytical Methodology
- E. Safety Investigations
- F. Proposed Regulation
- G. Not Applicable
- H. Environmental Assessment

Yours very truly,

Petitioner DuCoa L.P.

by Bruce D. King  
President  
Technical Products Division



**Technical Products Division**

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July 17, 1995

Dr. Henry Ekperigin  
Center for Veterinary Medicine  
U.S. Food and Drug Administration  
7500 Standish Place, HFV-226  
Rockville, MD 20855

Dear Dr. Ekperigin:

It has come to our attention that we did not address the issue of "Proposed tolerances for the food additive" in Section F of our Food Additive Petition entitled "*NATAMYCIN: MOLD RETARDANT IN BROILER CHICKEN FEED*" submitted to you on June 30, 1995.

The issue of "tolerances" is not applicable for natamycin when this additive is used as a mold retardant in broiler chicken feed.

Sincerely yours,

A handwritten signature in cursive script, appearing to read 'Bruce D. King'.

Bruce D. King  
President  
Technical Products Division

Franklin Carter  
3001 Rockborough Court  
Fort Collins, Colorado 80525  
Phone: (970) 223-9204  
August 18, 1995

Dr. George Graber, Director  
Division of Animal Feeds (HFV-220)  
Center for Veterinary Medicine  
7500 Standish Place  
Rockville, MD 20855

Re: FAP 6454

Dear Dr. Graber:

Enclosed are three copies of an amendment to the Food Additive  
Petition Number 6454.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Franklin Carter", written in dark ink.

Franklin Carter



SEP 11 1995

Food and Drug Administration  
Rockville MD 20857

SEP 6 1995

FAP 2234

Mr. Bruce D. King  
DuCoo  
Technical Products Division  
P.O. Box 219  
Highland, Illinois 62249-1105

Dear Mr. King:

We refer to your letter of June 30, 1995, in which you petitioned to use Natamycin as a mold retardant of *Aspergillus parasiticus*, *Penicillium rubrum*, and *Fusarium moniliforme* for up to 14 days in broiler chicken feed at a level of 11 ppm.

We have completed our initial review of your food additive petition, and have concluded it is acceptable for filing. A Notice of Filing will be published in the FEDERAL REGISTER pursuant to 21 CFR 571.1(i)(2).

Detailed review of your petition will be initiated, and you will be notified of its status within 90 days.

Regulation 21 CFR 571.1(h) specifies those portions of your petition that will, or will not, become available for public disclosure once the Notice of Filing appears in the FEDERAL REGISTER. In accordance with 21 CFR 571.1(i)(1), the date of this letter is regarded as the date of filing for the purposes of section 409(b)(5) of the Federal Food, Drug, and Cosmetic Act.

Please do not hesitate to contact us if you have any questions about this letter. Refer to FAP 2234 when making inquiries. Our telephone number is 301-594-1724.

Sincerely yours,

Stephen F. Sundlof, D.V.M., Ph.D.  
Director, Center for  
Veterinary Medicine



Technical Products Division

P.O. Box 219  
Highland, IL 62249-0219  
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October 26, 1995

Dr. George Graber, Director  
Division of Animal Feeds/Center for Veterinary Medicine  
7500 Standish Place  
HFV 226  
Rockville, MD 20855

REF: FAP 2234

Dear Dr. Graber:

As follow-up to a telephone conversation with Dr. Ron Bloom of the Environmental staff of CVM, I am enclosing the document he requested on compliance of our manufacturing facility with applicable Federal, State and Local occupational safety requirements.

I have already FAX'ed a copy to Dr. Bloom as he requested, and am sending this document to your attention as directed by Dr. Henry Ekperigin.

Sincerely,

A handwritten signature in cursive script that reads 'Dewey G. Barnes'.

Dewey G. Barnes, Ph.D.  
Director of Research and Development

DGB/kvt

Attachment

**NutriBasics** L.P.  
A DuPont  ConAgra Company

General Offices  
115 Executive Drive  
Highland, IL 62249-1269  
Phone: (618) 654-4424  
Fax: (618) 654-5659

October 26, 1995

TO WHOM IT MAY CONCERN:

This is to certify that, to the best of our knowledge, NutriBasics' manufacturing plant at Highland, Illinois is in compliance with all applicable federal, state and local occupational and safety requirements and is expected to remain in compliance when the natamycin premix is produced.



Earnie Parker  
Director,  
Quality and Regulatory Affairs  
NutriBasics L.P.

NOV 17 1995



## Colorado Quality Research, Inc.

1401 DUFF DRIVE, SUITE 700  
FORT COLLINS, COLORADO 80524  
(970) 484-0747  
FAX: (970) 484-8414

November 13, 1995

Dr. Bruce King  
DUCOA  
A DuPont/ConAgra Company  
P. O. Box 219  
115 Executive Drive  
Highland, Illinois 62249-0219

**RE: Project No. DUC-89-611**

Dear Dr. King:

This letter is just to let you know that FDA Investigators from the Denver District office were at our facilities on 11/2, 11/6, 11/7 and 11/8/95 for a general facility inspection and to inspect the above referenced GLP project that we conducted for you in 1989. They called again on 11/13/95 to conduct the exit interview portion of the inspection via a conference call.

We are happy to inform you that they did not issue a 483. Please give us a call if you have any questions.

Sincerely,

A handwritten signature in cursive script, appearing to read 'Bew'.

Beverly George, Ph.D.  
Vice President of Research

cc: Mr. Franklin Carter



Food and Drug Administration  
Rockville MD 20857

DEC 26 1995

FAP 2234

Bruce D. King, Ph. D  
DuCoa  
Technical Products Division  
P. O. Box 219  
Highland, Illinois 62249-1105

Dear Dr. King:

We refer to your food additive petition to amend regulations to allow for the use of natamycin, at the rate of 11 ppm, as a mold retardant of *Aspergillus parasiticus*, *Penicillium rubrum*, and *Fusarium moniliforme* for up to 14 days in broiler chicken feed. The petition was filed on September 6, 1995.

We need more time to complete our review of the petition and therefore, are extending the period of time allowed for review from 90 days to 180 days as permitted by the Code of Federal Regulations under Title 21, Part 571, Section 100, subsection b [21 CFR 571.100(b)].

Please do not hesitate to contact us if you have questions regarding this letter. Our telephone number is (301)-594-1731.

Sincerely yours,

George Graber, Ph. D.  
Director  
Division of Animal Feeds  
Center for Veterinary Medicine