



REGULATORY AFFAIRS

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January 19, 2000

The President's Council on Food Safety
Food and Drug Administration
Dockets Management Branch
(HFA-305)
5630 Fisher's Lane
Room 1061
Rockville, MD 20852

Docket 97N-0074 President's Council on Food Safety Strategic Plan

Viskase Companies, Inc (Nasdaq SmallCap: VCIC) through its subsidiary Viskase Corporation operates in the packaging products segment of the food industry.

Viskase Corporation (Viskase) is the leading producer of cellulosic food casings used in processing and packaging meat and poultry products. Other Viskase products include heat shrinkable plastic bags and specialty films for packaging and preserving fresh and processed meat products, poultry and cheese.

Viskase appreciates and thanks you for the opportunity to comment at this public meeting to discuss development of the President's Council on Food Safety Strategic Plan.

Viskase will also submit written comments to the FDA docket.

The President's Council on Food Safety needs a mechanism for the easily dealt with regulatory issues of food safety. Letters of no objection previously handled such easily dealt with regulatory issues.

Viskase urges the President's Council on Food Safety to restore priority to letters of no objection particularly when they are needed for food safety.

Letters of no objection are currently not being written even when the letter deals with food safety.

One such easily dealt with food safety issue is clearance of food packaging for food products during irradiation. Such packaging is composed of already reviewed components cleared for irradiation. Letters of no objection are a needed simple mechanism for clearance that must be restored.

Should you require further information or if clarification is needed, please contact me at 708-496-4623, FAX 798-496-4888.

TE Higgins

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Manager Regulatory Affairs

Attachment 1. **Letters of no objection for packaging – bags, food casings and films**
Attachment 2. **Follow up conversation with the FDA**

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Attachment 1.

Letters of no objection for packaging – bags, food casings and films

Viskase Corporation submitted and continues to submit formulas for packaging for FDA review. The visible output of FDA review is a letter. When the review is favorable, the approval letter is called a letter of no objection.

The packaging that Viskase Corporation submitted for review most recently is in the form of bags, film or food casing. The packaging is to be used during food product irradiation. This packaging is essential for food safety.

Viskase Corporation submitted:

- one formula in November 1998,
- 8 formulas in March 1999,
- 4 formulas in August 1999.

Viskase is having difficulty getting an output from the review process. The output is called a letter of no objection.

In March 1999, we were told that the formula that was submitted 4 months earlier met requirements. Viskase was told that we had verbal approval. A letter was promised. We have not received the letter.

At the end of 1999, we are told that such letters are no longer written. To make the matter worse, the reviewer has been promoted and no longer has anything to do with packaging approvals. We are very troubled because continuity has been lost. It is unacceptable to stop issuing letters of no objection.

Accordingly, it is essential that priority to writing letters of no objection is restored.

Attachment 2

Follow up conversation with the FDA:

What is the status of our requests for letters of no objection? The letters of no objection will not be written.

Are we doing something wrong? No, We want you to submit your packaging films

Why don't we get the promised letter? We are working on a priority for food safety. We are concentrating on petitions related to food safety and other petitions. Letters of no objection are ordinary correspondence. We no longer write ordinary correspondence.

But these letters are related to food safety. Yes, but they are also ordinary correspondence and we no longer write ordinary correspondence.

Should we resubmit as petitions? You could do that. It would not give you what you want. We would evaluate your request and convert it to a no objection request. That will result in a letter of no objection. Letters of no objection are ordinary correspondence. We no longer write ordinary correspondence.

But these letters of no objection are related to food safety. Yes, but they are also ordinary correspondence and we no longer write ordinary correspondence.

Should we resubmit as a premarket notification? You could do that. It would not give you what you want. We would evaluate your request and convert it to a no objection request. That will result in a letter of no objection. Letters of no objection are ordinary correspondence. We no longer write ordinary correspondence.

But these letters of no objection are related to food safety. Yes, but they are also ordinary correspondence and we no longer write ordinary correspondence.

None of this makes any sense.

Accordingly, it is essential that priority to writing letters of no objection is restored.