



**WARNING LETTER**  
**VIA EXPRESS**

Food and Drug Administration  
Center for Devices and  
Radiological Health  
2098 Gaither Road  
Rockville, MD 20850

AUG 4 2000

Mr. Nick N. Novicky  
Director, Research and Development  
Progressive Chemical Research, Ltd.  
1410 40<sup>th</sup> Avenue, N.E. #20  
Calgary, Alberta T2E6L1 Canada

Dear Mr. Novicky:

During an inspection of your firm located in Calgary, Alberta, Canada, on March 22-23, 2000, our investigator determined that your firm manufactures contact lenses. These products are devices as defined by Section 201(h) of the Federal, Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation, as specified in Title 21, Code of Federal Regulation (CFR), Part 820, as follows:

1. Failure to establish and maintain procedures to control the design of a device in order to ensure that specified design requirements are met, as required by 21 CFR 820.30. For example, there are no design controls for the Alberta Lens SM2.
2. Failure to validate with a high degree of assurance a process that cannot be fully verified by subsequent inspection and test, as required by 21 CFR 820.75(a). For example, the formulation changes used to produce the Alberta Lens SM2 have not been validated to ensure the product will consistently meet product specification.
3. Failure to maintain device master records, which adequately include, or refer to the location of, device specifications including appropriate drawings, composition, formulation and component specifications, as required by 21 CFR 820.181(a). For example, the device master record for the Alberta Lens S and Alberta Lens SM2 does not have appropriate specifications for the Dk value. More specifically, (a) the oxygen permeability for the Alberta Lens S is listed with a limit of minimum [REDACTED] Dk, and product is marketed as [REDACTED] and (b) the oxygen permeability for the Alberta Lens SM2 is listed with a limit of minimum [REDACTED] Dk, and product is marketed as [REDACTED]

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance system. You are responsible for investigating and determining the causes of the violations identified by the Food and Drug Administration. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Given the serious nature of these violations of the Act, all devices manufactured by Progressive Chemical Research, Ltd. Of Calgary, Alberta, Canada, *with the exception of the Alberta Lens S*, may be detained upon entry into the United States (U.S.) until these violations are corrected.

In order to remove the devices from this detention, it will be necessary for you to provide a written response to the charges in this Warning Letter for our review. After we notify you that the response is adequate, it will be your responsibility to schedule an inspection of your facility. As soon as the inspection has taken place, and the implementation of your corrections have been verified, your products may resume entry into this country.

We acknowledge receipt of your July 26 response to FDA 483 item #2 regarding lack of process validation for the formulation changes used to produce the Alberta Lens SM2. Our review of this response indicates that it appears adequate. We request that you please notify this office in writing within 15 days of the specific steps you have taken to correct FDA 483 items #1 and #3, including an explanation of each step being taken to identify and make correction to any underlying systems problems necessary to assure that similar violations will not recur. Please include any and all documentation to show that adequate correction has been achieved. In the case of future corrections, an estimated date of completion, and documentation showing plans for correction, should be included with your response to this letter.

If documentation is not in English, please provide an English translation to facilitate our review. Please address your response and any questions to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Enforcement II, Dental, ENT, and Ophthalmic Devices Branch, HFZ-331, 2098 Gaither Road, Rockville, Maryland 20850, to the attention of Mr. Eric Latish.

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Should you require any assistance in understanding the contents of this letter, do not hesitate to contact Ms. Leslie E. Dorsey at the letterhead address or at 301.594.4618 or FAX 301.594.4638.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Steven M. Niedelman", with a stylized flourish at the end.

Steven M. Niedelman  
Acting Director  
Office of Compliance  
Center for Devices and Radiological Health