

March 4, 1997

G.M. (Bud) Smith, Jr., President  
Apgee Corporation  
Hopewell Business and Industrial Park  
103 Corporation Drive  
Aliquippa, PA 15001-4863

Dear Mr. Smith:

This is a follow-up to my previous letter dated January 24, 1997, concerning the status of our review of your responses to our Confirmatory Action Letter (CAL), dated June 19, 1996, and your application for the model LB 31000 device. We have completed the review and analysis of your submittals dated November 27, 1996, December 4, 1996 and December 20, 1996, in response to the CAL and are in the process of forwarding the analysis of the responses to our Region I office for further action.

Based on several phone conversations with Ms Mary Dedola following issuance of the January 24, 1997, letter, there seems to be some confusion as to the actions initiated by that letter. I would like to clarify the actions that have been initiated and taken since issuance of that letter:

- Your responses to the CAL have been reviewed from the standpoint of acceptability for continued licensing of devices identified as having differences from the approved designs.
- We have identified the amendments required to your registration certificates based on the differences from the approved designs identified in your submittals. The required amendments have not been performed pending resolution of outstanding issues raised in your responses to the CAL.
- As requested, your application, dated July 30, 1996, requesting amendment to Apgee's registration certificates to authorize manufacture and distribution of previously approved Berthold devices in the US, has been voided and no further action has been taken on this application.
- Your application for registration of the Model LB 31000 series devices that you wish to manufacture and distribute in the US has been assigned to a reviewer and is in the process of being reviewed.

If you have any questions concerning this matter, please contact me at (301) 415-5847 or Mr. Steven Baggett at (301) 415-7273.

Sincerely,

*131*  
Douglas A. Broadus, Mechanical Engineer  
Sealed Source Safety Section  
Medical, Academic, and  
Commercial Use Safety Branch  
Division of Industrial and  
Medical Nuclear Safety, NMSS

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