DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAR 18 1986

George W. Siebert
Director of Safety and
Occupational Health Policy
Office of the Assistant Secretary of Defense
Washington, D.C. 20301-4000

Ref. Doc.: 76EL-01DoD

Dear Mr. Siebert:

This letter is in response to your January 6, 1986 request for amendment of exemption 76EL-01DoD to eliminate the requirement for an annual report. Under this exemption, laser products which are intended to be used in combat or in training for combat were exempted, as necessary, from the performance standard for laser products as provided in 21 CFR 1010.5. These products were also exempted from the reporting requirements of 21 CFR 1002.10 and 1002.12 under the authority provided in 1002.51.

At the time this exemption was granted, the performance standard for laser products was not yet in effect, and the Agency could not reasonably anticipate the type or magnitude of problems which would be encountered, or the efficacy of the various mechanisms provided in the standard in addressing these problems. The Agency elected at that time to maintain what was considered the minimal regulatory position consistent with its responsibility for Public Health, and, therefore, the annual reporting requirement was retained. Now the Center has almost ten years of experience in administering these regulations, and has received nine annual reports from your department. At this point in time, it is my judgment that these reports on exempted products are no longer needed as a monitoring tool.

Therefore, as provided by 21 CFR 1010.5(e)(2), the Department of Defense (DoD) exemption is hereby amended to revoke the requirement for an annual report. The effective date of this amendment is September 1, 1985. Please note that while DoD will no longer need to submit the subject annual reports, it will still be expected to maintain the types of records on which this report was based. This information may be requested when we need to confirm a manufacturer's claim that he is producing laser products for DoD procurement and that his products are indeed subject to exemption. Your continued close cooperation in providing pertinent information upon request is recognized and appreciated, and, of course, such requests will be limited to information which does not impact on national security.

I trust that this resolution of the issues satisfactorily addresses your concerns.

Sincerely yours,

John C. Villforth
Director
Center for Devices and
Radiological Health