



JAN 26 2006

Food and Drug Administration
Rockville MD 20857

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Ref: FDA Docket No. 2005V-0499
Accession Nos. 05A2822-00
0512821-00

Mr. Don Grise
Laser System Program Manager
Night Vision Equipment Company
2751 N. Mendecino Dr.
Prescott Valley, Arizona 86314

Dear Mr. Grise:

In accordance with 21 CFR 1010.4(c)(1), notice is given that the petition from Night Vision Equipment Company dated December 19, 2005, for a variance from certain requirements of 21 CFR 1040.10 and 1040.11 is hereby granted. This variance, under the conditions stated below, will allow the introduction into commerce of the products described in paragraph D

A. Variance Number

2005V-0499

B. Effective Date

In accordance with 21 CFR 1010.4(c)(1), his variance shall become effective on the date of this letter.

C. Termination Date

This variance shall be terminated December 31, 2010.

D. Product for Which Variance is Granted

This variance is granted for the infrared Class IIIb Model GCP-1A and Model GCP-2 pointer/illuminator manufactured by Night Vision Equipment, Inc.

E. Provisions from Which Variance is Granted

This variance is granted from the following requirements of 21 CFR 1040.10 and 1040.11:

1. 21 CFR 1040.11(b)(3), which restricts the class of alignment laser products such as the Models GCP-1A and GCP-2 to Class IIIa,
2. 21 CFR 1040.10(f)(3) which requires Class IIIb laser systems to incorporate remote interlock connectors,
3. 21 CFR 1040.10(f)(4) which requires Class IIIb laser systems to incorporate key controls.
4. 21 CFR 1040.10(f)(5) which requires Class IIIb laser systems to incorporate emission indicators that provide a visible or audible signal. This section also requires that indication be given sufficiently prior to emission to permit appropriate action to

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avoid exposure to laser radiation in excess of the accessible emission limits of Class I (1040.10(f)(5)(ii)). Also, this section requires that visible indicators be visible through laser protective eyewear designed for the applicable wavelength(s), (1040.10(f)(5)(iv)).

5. 21 CFR 1040.10(g)(2)(iii) which requires warning logotype labeling affixed to Class IIb laser systems to have a white background with black lettering in positions 1, 2, and 3 of this label.

All other provisions of 21 CFR 1040.10 and 1040.11 remain applicable to the laser product.

F. Conditions under Which Variance is Granted

In lieu of the requirements referred to in Item E above, the following conditions shall apply to the infrared Class IIb Model GCP-1A and Model GCP-2 products manufactured under this variance.

1. The sales of these laser pointing/illuminating devices shall be restricted to:

- 1.1. Government and law enforcement agencies only under a direct purchase order from the agency and shall not be sold to individual law enforcement personnel. Sale to Department of Defense agencies is not authorized under this variance.
- 1.2. Contract purchasers acting for a United States Government agencies for purchase of products identified in item D above providing the contractor provides your company with documentation confirming that:
 - a. The procurement is made by the contractor acting as an agent for a United States Federal government agency to which you would otherwise be permitted to make a direct sale.
 - b. The number of products being procured by the contractor is the same as the number ordered by the United States Federal government agency.
 - c. All of the products ordered by the United States Federal government agency are actually delivered to the agency.
- 1.3. Non-government organizations listed in Attachment A that operate and provide security for critical facilities under the conditions that:
 - a. The organization has provided evidence of its need for the products in the operation and protection of the critical facility.
 - b. The organization maintains an active program of training its employees in the safe use of the weapons and laser systems to be used.
 - c. The organization maintains a property log indicating the responsible party having control of these devices.

2. The user information to be supplied with each pointer/illuminator shall include:

- 2.1. Detailed written instructions on the radiation hazards of the devices and on its safe use including warnings against eye exposure within the nominal ocular hazard distance while being used in a training program.
- 2.2. A statement that sale of this product is restricted to Federal, State, local government and law enforcement agencies and the critical facility operator organization listed in Attachment A only through a direct purchase order and shall not be sold to individual personnel of these agencies or organizations
- 2.3. A statement that the batteries shall be removed when the product is not intended to operate to prevent unauthorized use.
- 2.4. A statement that it is also necessary and intended that the invisible beam emitted by these devices be viewed by the user through night vision equipment.
3. The product incorporates a normally off/momentarily on pressure switch that serves the function of both the emission indicator and beam attenuator within the intent of the regulations.
4. The product will incorporate a safety feature that prevents the device from emitting non-eye-safe levels of radiation when used in the training mode.
5. Advertising and sales literature used for promotion of this product will include a statement that the sale of these devices is restricted to Federal, state and local government and law enforcement agencies and the critical facility operator organization listed in Attachment A through a direct purchase order.
6. Alternate labeling will include a black background with white lettering in positions 1, 2, and 3 of the warning logotype label.

This variance also recognizes that an audible or visible emission indicator and the other specified requirements could seriously compromise the safety of law enforcement officers and security personnel in the performance of their duties.

G. Basis for Approval of Variance

The Center for Devices and Radiological Health has determined, in accordance with 21 CFR 1010.4(a), that the GCP-1A and GCP-2 devices utilize alternate means for providing radiation safety or protection equal to that provided by products of similar design meeting all the requirements of the standard and/or that the specified requirements are not appropriate for laser products for this intended use.

The intended use of this product is by government law enforcement agencies or critical facility operator security personnel only in the routine execution of their duties, and under conditions that could seriously compromise their safety should their position be revealed by a sound or a light or function of the product be impaired by delay of emission of the targeting beam or when preparing the product for operation.

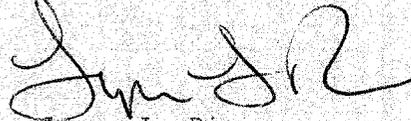
H. Certification Label

The certification label required by 21 CFR 1010.2 shall be modified in accordance with 21 CFR 1010.4(d) to state, "Conforms to 21 CFR 1040, laser products, except as authorized by Variance 2005V-0499 effective

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This variance action is available for public disclosure in the Dockets Management Branch, Food and Drug Administration. The variance will remain in effect until the termination date unless a determination is made that the variance should be amended or withdrawn, or the provisions of the standard from which the variance is granted are amended before the termination date.

Sincerely yours,



Lynne L. Rice
Director
Office of Communication, Education,
and Radiation Programs
Center for Devices and
Radiological Health

cc: FDA Dockets Management Branch, Docket No. 2005V-0499

Variance Attachment A
Variance No 2005V-0499
NIGV (Night Vision Equipment Co.)

The following non-governmental security organization is authorized to purchase the infrared laser aiming device described in paragraph D of this variance.

None are identified