

2 Harris Court A4, Monterey, California 93940, U.S.A.
(831)373-0701 FAX(831)373-0903 E-MAIL:Sales@laserdevices.com
www.laserdevices.com

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By Federal Express Standard Overnight

Documents Management Branch
(HFA-305)
Food and Drug Administration
5630 Fisher's Lane, Room 1061
Rockville, MD 20852

**Re: 21 CFR 1040.10 (f)(3- 5) , 1040.11 (b)(3)
Variance Application for Infrared Laser Aiming Devices**
**Models: Dual Beam Aiming Laser (DBAL)
Dual Beam Aiming Laser Infrared Illuminator (DBAL-IR)
Multi-Operational Aiming Laser Device (MOLAD)
Dual Beam MP5 (DBMP5)
Dual Beam MP5 (DBMP5-IR)
Offset Tactical Aiming Laser Infrared (OTAL - IR)
Inline Tactical Aiming Laser (ITAL - IR)
Other Laserscope products equipped with an IR diode.**

Dear Sir or Madam:

This letter shall serve as Laser Devices, Inc.'s ("LDI's") application per 21 CFR 1010 requesting a variance from the Laser Performance Standards of 21 CFR 1040 *et seq.* that will allow for the sale of it's infrared (IR) family of Class IIIb lasers to its properly authorized GSA Schedule holder Quantico Arms. The purpose of this variance request is to allow Quantico Arms to purchase and stock critical inventory items for sale to U.S. Government agencies so that the items can be delivered quickly to the end-users. We believe that this variance, if granted, will enhance national security by significantly reducing the delays associated with the current FDA variance requirements established in 02V-0382.

I. Description of Product and Background Information.

Laser Devices, Inc. is a manufacturer of laser aiming devices and tactical flashlights for law enforcement and military users. A number of the devices, including those listed above, are equipped with an infrared laser diode and have a Class IIIb safety designation. These devices are sold domestically to Federal, State and Local law enforcement agencies in accordance with the requirements established by FDA Variance 02V-0382. In addition, LDI has recently started to sell a few of its IR lasers to the U.S. Military pursuant to the requirements established by FDA Laser Notice 52.

The following issues arose over the last year and have limited LDI ability to supply U.S. law enforcement and military agency customers with the equipment that they require in a timely fashion:

1. The need to have a convenient way for Federal agencies to order moderate quantities of IR sighting devices without having to conduct a formal tender for the equipment. LDI has addressed this problem by selecting a vendor with the ability to list and promote our products on the GSA law enforcement schedule.

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AMD

2. The need to provide for expedited delivery of enforcement equipment to agencies that need it. LDI would like to address this issue by establishing an inventory with its GSA contractor that can be used to meet urgent agency requirements.

As you undoubtedly know, the Federal Government purchases a vast amount of equipment and services through the mechanism of the GSA Schedule. These purchases are typically made through the vehicle of a GSA Schedule held by distributors that specialize in marketing and selling products to the government. Occasionally, larger manufacturers will also hold a GSA Schedule, but this generally requires a specialized sales and marketing staff that focus exclusively on government purchasers. Smaller manufacturers, like LDI, do not have this specialized capability and typically partner with a distributor that specializes in government sales.

The GSA Schedule makes it easier for agencies to purchase supplies and services by ensuring that the government has already negotiated fair and reasonable pricing. Using a GSA Schedule also allows the purchasing agency to make a "Best Value" determination without having to conduct a formal tender. Orders placed against a GSA Schedule meet the requirements for full and open competition and makes it easier for agencies to meet their small business, woman owned business and disadvantaged business objectives.

In the past, LDI has listed its lasers on the GSA Schedule for Law Enforcement and Security Equipment (Solicitation 7FCI-L3-03-0084B) held by a small disadvantaged business. Unfortunately, without the ability to stock or demonstrate the IR equipment our current GSA schedule holder has had considerable difficulty in promoting and selling LDI's infrared products. Over the last year our current GSA Schedule holder lost at least one nice order for a Dual Beam Aiming Lasers because they were unable to meet the delivery time required by the customer.

In other cases, agencies that need IR lasers have been delayed in receiving the units because the current GSA schedule holder was unable to stock the IR items. LDI as a small manufacturer with a large number of products focuses its efforts at building products to fill existing orders from dealers and distributors. Compounding the problem is the fact that LDI's current production cycle is currently averaging between 20 to 30 days. Unfortunately, many of our Federal agency customers seem to need the equipment faster than LDI can manufacture it.

II. Proposed Solution to the Supply Problem.

LDI has recently formed a distribution agreement with a new GSA Law Enforcement Schedule contractor, Quantico Arms & Tactical Supply Inc. ("Quantico Arms") located at 253 Potomac Ave, Quantico, Virginia 22134. The General Manager of Quantico Arms is David Hensley, a retired U.S. Marine Major. Quantico Arms is a licensed firearms dealer that specializes in supplying tactical and law enforcement equipment to Federal Agencies through its GSA Schedule. In addition, Quantico Arms maintains a specialized sales staff that is experienced in demonstrating and promoting firearms and other law enforcement equipment. These sales are typically handled through its GSA Law Enforcement Schedule.

Quantico Arms typically stocks enough equipment to meet urgent requirements for tactical equipment. This allows it to win sales based on the ability to deliver product on an expedited basis. Mr. Hensley has expressed the need to stock a selection of IR aiming lasers that he would market and sell to his

Federal customers. Quantico Arms has also indicated that it is willing to comply with the reasonable restrictions on the sale and marketing of the IR devices to ensure that this equipment is only sold to those qualified customers described in LDI's current FDA exemption.

Proposed Exemption Requirements.

LDI would propose that the current variance 02V-0382 be amended to allow limited sales of IR Class IIIb devices to Quantico Arms for sale via its GSA Law Enforcement Schedule as follows:

1. Sales are limited to Agencies that are authorized to purchase via the GSA Schedule. As far as we can determine individual law enforcement officers are not authorized to purchase personal equipment on the GSA Schedules.
2. That all IR lasers sold to Quantico Arms bear a special label identifying the source of the equipment. The proposed label is as follows:

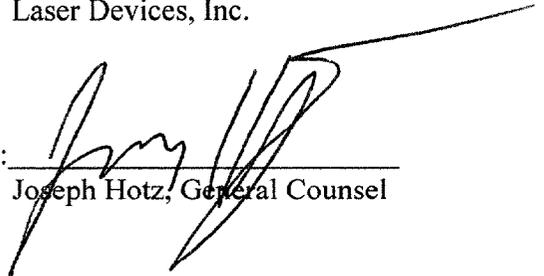
Supplied by Quantico Arms
Resale, loan or donation prohibited
by Federal Law 21 CFR 1040 et. seq.

3. That Quantico Arms will provide a copy of the GSA purchase order to LDI within 30 days after delivering the equipment to the agency customer.

In our opinion the proposed safeguards, are adequate to ensure that the Class IIIb products will not be sold commercially. Moreover, this arrangement would benefit the Federal Agencies charged with protecting homeland security by providing them with a readily accessible source for this type of equipment.

If you have any questions or comments concerning the above, please do not hesitate to contact me directly.

Very Truly Yours,
Laser Devices, Inc.

By: 
Joseph Hotz, General Counsel