



DEPARTMENT OF HEALTH & HUMAN SERVICES

M 807N

Public Health Service

Food and Drug Administration  
2098 Galther Road  
Rockville MD 20850

HFI-35 6/3/97  
2.28

MAY 7 1997

WARNING LETTER

Ref:OC:11-1750

via FEDERAL EXPRESS

Mr. Larry J. Smith, President  
Romer, Inc.  
5145 Avenida Encinas  
Carlsbad, California 92008

Dear Mr. Smith:

This letter is written to advise you of items of noncompliance, listed below, with the Federal regulations and standards applicable to laser products encountered during an inspection on February 6, 1997, by Ms. Serrah Namini, Electro-Optics Specialist of the Food and Drug Administration Pacific Regional Staff. The products included the Homer and ELVIS laser systems. During the inspection you agreed to correct the deficiencies noted by Ms. Namini; however, a review of our files fails to show any action to date on your part.

1. 21 CFR 1010.2. The products lacked certification labels as required by this section.
2. 21 CFR 1010.3. The products lacked identification labels as required by this section.
3. 21 CFR 1040.10(f)(5). The products lacked emission indicators as required by this section.
4. 21 CFR 1040.10(g)(2)(ii). The products lacked warning logotype labels as required by this section.
5. 21 CFR 1040.10(g)(5). The products lacked aperture labels as required by this section.
6. 21 CFR 1040.10(h)(1). The user instructions lacked the information required by this section.

Section 538(a) of the Federal Food, Drug, and Cosmetic Act (the Act), Chapter V, Subchapter C (formerly the Radiation Control for Health and Safety Act of 1968) prohibits any manufacturer from certifying or introducing into commerce laser products which do not comply with the standard. This section also prohibits any manufacturer from failure to establish and maintain required records or to submit required reports. Failure to respond to this letter may be considered to be a violation of paragraph 538(a)(4) of the Act. The Food and Drug Administration (FDA) is prepared to invoke regulatory actions if you fail to comply with these requirements. These actions may include an injunction and/or imposition of civil penalties as provided for in Section 539. Persons failing to correct violations and/or continued violations of the Act are subject to civil penalties of up to \$1,000 per violation and up to a maximum penalty of \$300,000 without further notification by the FDA. In cases where a foreign manufacturer fails to respond, penalties may be imposed upon importers. You must respond in writing within 15 days of receipt of this letter to one of the options listed below. In your response you must also provide the number of the referenced products which have been produced, and the number of such products that have left the place of manufacture. In addition, if the product distribution was confined to specific geographical areas of the United States, please specify those areas.

1. Refutation - You may submit your views and evidence to establish that the alleged failures to comply do not exist.
2. Exemption Request - You may request an exemption from user and dealer/distributor notification and from obligation to correct the violative products. Your request must include the grounds upon which such exemption is requested (see 21 CFR 1003.30 and 1003.31).
3. Purchaser Notification and Corrective Action - If you neither refute the noncompliance nor request an exemption, then you must: (a) notify purchasers and dealers/distributors of the violative products as specified in 21 CFR 1003.10(b), and (b) submit a written corrective action plan (CAP) to fulfill your obligation under 21 CFR 1004.1 to repair, replace, or refund the cost of the violative products.
  - a. Notification Letter - Requirements for preparation of notification letters are prescribed in 21 CFR 1003.21 and 1003.22. A copy of the notification letter(s) sent to purchasers and dealers must also be sent to the FDA. It is recommended that you submit a draft of this letter to us for review.
  - b. Corrective Action Plan - Instructions for preparation of a CAP may be found in 21 CFR 1004.2, 1004.3, or 1004.4.

If you request additional time to prepare your refutation, notification, CAP, or evidence to support a requested exemption, you must provide the reasons for any delays and a reasonable target date for the full submission of your response. Be aware that if an acceptable CAP cannot be prepared promptly, you may be required to proceed with interim notification to affected persons as required by 21 CFR 1003.11(c) and 1003.21. Therefore, you are encouraged to immediately begin your preparation of accurate user location lists. The following failures to comply with the regulations regarding reports and record keeping were observed:

1. 21 CFR 1002.10. Our records fail to indicate submission of a product report as required by this section.
2. 21 CFR 1002.20. Romer, Inc. has failed to establish and maintain records as required by this section.

Based on the findings listed above, the Center for Devices and Radiological Health (CDRH) declares that Romer, Inc. has failed to conduct a testing program which ensures compliance with the applicable performance standard. The CDRH therefore, under authority of 21 CFR 1010.2(c), disapproves the testing and quality control program for laser products at Carlsbad, California.

This disapproval means that your firm is prohibited by Sections 534(h) and 538 of the act from:

1. certifying the electronic products manufactured under the disapproved testing program,
2. introducing or importing products into the United States (U.S.) commerce which bear false and misleading certification, that is, products certified under the testing program which has been disapproved, and
3. introducing or importing into the U.S. commerce any product which does not have the certification label permanently affixed to the product, as required by 21 CFR 1010.2.

To resolve this matter, you must submit all the information required under 21 CFR 1002.10 such that the CDRH can determine that Romer, Inc. is in compliance with the Act, that the subject products comply with the performance standard, and that the testing program is in accord with good manufacturing practices.

**The CDRH will advise you whether your submittal is satisfactory.**

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Submit your response to: Director, Division of Enforcement III (HFZ-340), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850. You are also requested to send a copy of your response to: Director, Compliance Branch, Los Angeles District Office, Food and Drug Administration, 19900 MacArthur Blvd., Suite 300, Irvine, CA 92715. If you have further questions on these requirements, please contact the Electronic Products Branch at (301) 594-4654.

Sincerely yours,



Lillian J. Gill  
Director  
Office of Compliance  
Center for Devices and  
Radiological Health