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WARNING LETTER

Ref: OC: II - 1844

via FEDERAL EXPRESS

Mr. Robert S. Rubin, President
CMI Incorporated
960 North Shore Dr.
Lake Bluff, Illinois 60044

Mr. Mitchell Kuan
Sales Manager
Sirus Technology Corp.
No. 6-16, S Kao Shan Ting Yang Mai
Tao Yuan, Taiwan
R.O.C.

Gentlemen:

This is in response to Mr. Rubin's letter of January 7, 2000, concerning an accession number for a laser product report and a shipment of laser pointers being detained at the Chicago port of entry. The entry number for this shipment is 495-0621524-0. Attached to Mr. Rubin's letter was another letter dated November 3, 1998, addressed to Mr. Kuan, Sirus Technology Corp., acknowledging receipt of a laser product report describing laser pointer modules numbers 83-010323-034 and 83-01-323-072. The report describes these modules as laser components. They were not considered to be certified laser products. The November 3, 1998 letter assigned number 9821948-00 to the report.

Upon further review of that report, it has been determined that these models were laser components and not complete laser pointers and number 9821948-00 had erroneously been assigned to the report. This number was subsequently deleted from our files, and the submission for these laser modules was assigned a new number 98R2249. However, since the products in the shipment in question are complete laser pointers, this new number cannot be used to signify that the manufacturer has submitted a report on the pointers in question.

Mr. Rubin also submitted a single sample of a pointer taken from this shipment. The sample included labeling that identified the pointer as "Fat Cat Laser". There is no other identifying model number given for this product. We have no report in our files that identify this pointer as being manufactured by Sirus Technology Corporation. The only identification is the name "CMI Incorporated" imprinted on the information card (user instructions) included as an insert in the plastic container in which the pointer was packaged. No address for CMI Incorporated was given.

This product is a round gold colored key-chain type pointer measuring 1/2 x 2 1/2 inches in size classified as a Class IIIa laser product. By the use of diffracting optics in the removable end cap it projects an image of a mouse. This cap is not permanently attached to the barrel of the pointer and is easily removed by simply unscrewing the cap. With the cap removed it projects a bright red dot.

This letter is to advise you of items of noncompliance with the Federal performance standard for laser products (21 CFR 1040.10 and 1040.11) encountered during testing of the sample laser pointer submitted by Mr. Rubin.

Radiation output of the sample was determined by using a Coherent Labmaster test instrument. These measurements revealed the following:

1. With the end cap in place, the maximum radiation output measured was 2.5 mW. This measurement does not exceed the Class IIIa limit of 5 mW.
2. With the end cap removed the maximum radiation output measured was 8.5 mW. Since the end cap containing the diffracting optics is so obviously and easily removable, we believe that the product must be classified based on the output level accessible with the end cap removed. Our measured value under this condition was 8.5 mW, which exceeds the limit of Class IIIa. We therefore conclude that the product is in fact Class IIIb and fails to comply with the following requirements of the Federal performance standard for laser products applicable to Class IIIb laser products: 21 CFR 1040.10(f)(3)-Remote interlock connector; 1040.10(f)(4)-Key Control; 1040.10(f)(5)-Emission indicator and 1040.10(f)(6)-Beam attenuator.
3. The product is also in violation of 21 CFR 1040.11 which limits the output of laser pointers to no greater than 5 mW.

Although a Class IIIa warning logotype that incorporated a certification statement was permanently affixed to the pointer a review of the labeling requirements applicable to a Class IIIa laser product revealed the following items of noncompliance were noted:

1. The pointer lacked an aperture label as required by 21 CFR 1040.10 (g)(5),
2. There was no identification label affixed to the product as required by 21 CFR 1010.3 or included in the user information,
3. The user information failed to incorporate a reproduction of the warning logotype label required to be affixed to the pointer and failed to indicate the location of this label on the pointer,

4. The user instruction failed to include the "Caution- Use of control" statement required by 21 CFR 1040.19 (h)(iv).

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 been introduced into U.S. commerce. 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.

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Mr. Mitchell Kuan

- 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-Product reports. A product report has not been submitted for the Fat Cat Laser pointer as required by this section.
2. 21 CFR 1002.13-Annual reports. Annual reports have not been submitted as required by this section.

When you have completed any production changes necessary to assure compliance of future units and you have submitted the required reports and report supplements, you may resume introduction of these products into commerce.

Your response should be sent 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, Chicago District Office, Food and Drug Administration, 300 Riverside Plaza, 5th Floor, Suite 550 South, Chicago, Illinois 60606

If you have further questions on these requirements, please contact Frank Mackison of the Electronic Products Branch at (301) 594-4654.

Sincerely yours,



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