



Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

JUN 22 1999

WARNING LETTER

via FEDERAL EXPRESS

Ref:OC:II-1828

Mr. Stephen Jeng  
Managing Director  
Sean & Stephen Corporation  
4F, No. 3, Lane 335, Sec. 4  
Hsin-Yi Road, Taipei  
TAIWAN, R.O.C.

Dear Mr. Jeng:

This letter is written to advise you of items of noncompliance with the Federal laser performance standard encountered through an evaluation of your Funchy yo-yo Laser, Model 4093 that was provided as a sample for our evaluation.

1. 21 CFR 1040.10(f)(6). The product lacks a beam attenuator. The only way to terminate the beam of the sample provided is to remove the batteries or wait until batteries run out. This does not meet the requirements of this section.
2. 21 CFR 1040.10(h)(1)(i). The user instructions are inadequate in that they fail to include adequate instructions for the operation of the laser as required by this section.
3. 21 CFR 1040.10(g)(10). The follow-up sample provided failed to include the required labeling as 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 539(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 30 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 manufacturer. 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 does not exist.
2. Exemption Request - You may request an exemption from user and dealer/distributor notification and from obligations 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 reason 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.

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, Minneapolis District Office, Food and Drug Administration, 240 Hennepin Avenue, Minneapolis, MN 55401. If you have further questions on these requirements, please contact Susan Jensen of the Electronic Products Branch at (301) 594-4654.

Sincerely yours,



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

Cc: Mr. Dean DeHarpporte  
President  
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Cc: Jensen  
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Frye (HFR-MA450)  
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MIN-DO Compliance Branch (HFR-MW340)  
RRHR-MW19  
DE3 Chron File  
OC Read File  
OC Chron File  
HFC-135  
HFC-210  
HFI-35 (purged)