



SEP 6 2000

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850WARNING LETTER

Ref:OC:I1-1865

via FEDERAL EXPRESS

Mr. Doo Sun Yoo  
President  
New Pacific Inc.  
1349 Kapiolani Blvd.  
Honolulu, Hawaii 96814

Dear Mr. Doo:

This letter is to notify you that the Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA) hereby disapproves the quality control and testing program for the laser light show produced by New Pacific, Inc., aka Venus Nightclub, 1349 Kapiolani Boulevard, Honolulu, Hawaii. This action is taken under the authority of the United States' (U.S.) Federal Food, Drug, and Cosmetic Act, Chapter V, Subchapter C - Electronic Product Radiation Control (hereafter referred to as "the Act").

Based on the findings listed below, the CDRH declares that New Pacific, Inc., aka Venus Nightclub has failed to conduct a testing program which ensures compliance with the applicable performance standard and your variance, Number 00V-1125. The CDRH therefore, under authority of 21 CFR 1010.2(c), disapproves the testing and quality control program for laser light shows produced at Venus Nightclub, 1349 Kapiolani Blvd., Honolulu, Hawaii.

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.

The following conditions were observed during an inspection of the laser projection system installed and operated under variance number 00V-1125. The inspection was conducted at the Venus Nightclub on the evenings of August 2 and 3, 2000 by Mr. Kenneth A. Miles, Regional Radiological Health Representative, Pacific Region, U.S. Food and Drug Administration, 1301 Clay Street, Suite 1180-N, Oakland, CA 94612. The following non-compliant conditions with the Federal laser performance standard or your variance were observed:

1. Variance Attachment A. Condition 8b: The show was under the control of the music director (disc jockey) and not under the control of a person trained to operate the projection equipment as required by this condition. Also, the music director (disc jockey) observed operating the equipment was not located in a position that permitted direct observation of all beam path at all times during operation of the show as required by this variance condition.
2. Variance attachment A. Condition 12: Records, such as quality assurance procedures, variance application approval and current operating procedures and records relating to each particular show were not available at the site as required by this section.
3. Variance Attachment A. Condition 6. Mirrors incorporated in the show beam effect were less than the required 3 meters about the floor of the nightclub where the audience is permitted

During the inspection Mr. Miles observed that the key control for the projections system was not removed when the system was taken out of operation. While this is not considered a violation of your variance it is a poor safety practice and should not continue. Also, Mr. Miles was told that the Mobolazer SC-100 controller was previously found to operate improperly causing the laser beams to be scanned into the audience. Although not observed by Mr. Miles during the inspection, scanning, projection, or reflection of laser beams into the audience is prohibited by Condition 5 of Variance Attachment A.

You are not being requested to submit a formal corrective action plan at this time; however, all future production must comply with the standard and your variance. Persons failing to correct violations may be subject to regulatory action. If you feel that

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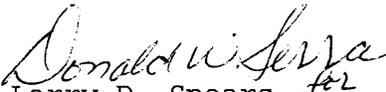
the alleged failures to comply do not exist, you may present your views and evidence within 15 days of receipt of this letter.

To resolve this matter, you must submit all the information required under 21 CFR 1002.10 such that the CDRH can determine that laser light shows installed and operated by New Pacific, Inc., at the Venus Nightclub, 1349 Kapiolani, Blvd., Honolulu, Hawaii is in compliance with the Act, the performance standard and the conditions of your variance, and that the testing program is in accord with good manufacturing practices.

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

You must 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.

Sincerely yours,

  
Larry D. Spears *for*  
Acting Director  
Office of Compliance  
Center for Devices and  
Radiological Health

CC: Department of Health  
Environmental Health Services Division  
591 Ala Moana Boulevard  
Honolulu, Hawaii 96813