



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

May 6, 2004

VIA CERTIFIED MAIL

In reply refer to Warning Letter SEA 04-25

Sherman L. Watson, Owner
Talon Acrylics, Incorporated
850 Northeast 102nd Avenue
Portland, Oregon 97220

WARNING LETTER

Dear Mr. Watson:

During an inspection of your firm located in Portland, Oregon, from December 22, 2003 and February 4 through February 12, 2004, our investigator determined that your firm manufactures liquid thermoplastic products for the dental industry. These dental products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our inspection disclosed that your devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) requirements for the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820 as follows:

1. Failure to establish and maintain procedures for implementing corrective and preventative actions [21 CFR 820.100(a) and (b)]. Specifically you have no procedures for Corrective and Preventive Action and have no documentation for these operations.
2. Failure to maintain all records required [21 CFR 820.180]. Specifically you do not maintain the following records as required:
 - a. records of finished product acceptance [21 CFR 820.184 (d)],
 - b. Quality System Records or procedures of how or when to conduct quality audits [21 CFR 820.22, 820.186].

You should take prompt action to correct these violations and prevent their reoccurrence in the future. Failure to promptly correct these violations may result in FDA initiating regulatory action without further notice. These actions include, but are

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not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. Also, other federal agencies are informed about the Warning Letters we issue, such as this one, so they may consider this information when awarding government contracts.

Please notify us in writing within fifteen (15) working days from the date you received this letter, what steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Send your written reply to the Food and Drug Administration, Attention: Bruce Williamson, Compliance Officer, 22201 23rd Drive SE, Bothell, WA 98021. If you have questions regarding any issue in this letter, please contact Mr. Williamson, Compliance Officer, at (425) 483-4976.

Sincerely,

Celeste M. Corcoran

for

Charles M. Breen
District Director