



1580b

December 2, 1996

Food and Drug Administration  
Seattle District  
Pacific Region  
22201 23rd Drive S.E.  
P.O. Box 3012  
Bothell WA 98041-3012

Telephone: 206-486-8788  
Fax: 206-483-4996

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 97-05

K.C. Yee, Ph.D.  
President  
AmeriTek, Inc.  
7030 35th Avenue NE  
Seattle, Washington 98115

WARNING LETTER

Dear Dr. Yee:

During an inspection of your firm on October 15-17, 1996, Engineers Teri L. Colbert and Neil F. Sheller determined that your firm manufactures a human chorionic gonadotropic test strip labeled as the One Step INSTA Strip (pouch labeled HCG Urine). This is a device within the meaning of Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The One Step INSTA Strip (HCG Urine) is misbranded within the meaning of section 502(f)(1) of the Act in that the labeling does not bear adequate directions for use because it is not labeled in accordance with Title 21, Code of Federal Regulations (CFR), section 809.10 (enclosed). For example, a package insert does not accompany each device as required by 21 CFR 809.10(b). Additionally, there is no written agreement, as required by 21 CFR 801.150 (enclosed), with those establishments further processing, labeling, or repacking the device which would exempt the One Step INSTA Strip (HCG Urine) from the label requirements of section 502(b) and (f) of the Act.

The One Step INSTA Strip (HCG Urine) is misbranded under section 502(a) of the Act in that the labeling for the device, namely the instructions for use insert entitled, "One Step hCG Pregnancy Test Kit", contains the following statements: "It is licensed as a Medical Device Establishment by the United States Food and Drug Administration (FDA)\*" and, "\*Medical Device Establishment Registration Number:3025672", which are misleading in accordance with 21 CFR 807.39 (enclosed) because such statements create an impression of official approval due to registration or possession of a registration number.

Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products.

K.C. Yee, Ph.D., President  
AmeriTek, Inc.  
Page 2

Additionally, this labeling also contains the statement "USFDA #K953606", which is misleading in accordance with 21 CFR 807.97. This statement creates an impression of official approval of a device which is complying with the premarket notification regulations. This device was not approved by the FDA, but was determined to be substantially equivalent within the meaning of section 513(i)(1)(A) of the Act.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. Federal agencies are advised of the issuance of all Warning Letters so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to take prompt corrective action may result in regulatory action without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) days of receipt of this letter of the specific steps you have taken to correct the noted violation. If corrective action cannot be achieved within 15 working days, please state the reason for delay and the time frame in which correction will be accomplished. Your reply should be directed to Thomas S. Piekarski, Compliance Officer, at the above address for the Seattle District.

Sincerely,

  
Roger L. Lowell  
District Director

Enclosures:

21 CFR 801.150  
21 CFR 807.39  
21 CFR 807.97  
21 CFR 809.10

cc: H.C. Yee, Ph.D., Vice President  
AmeriTek, Inc.  
7030 35th Avenue NE  
Seattle, Washington 98115

cc: HFA-224  
HFC-210 (via Banyan)  
HFZ-321, DOE I, IVD Branch/Jan Welch  
SCD/HFI-35 (redacted copy)

cc: w/copy HFZ-321 WL Approved Memo dtd 11/22/96  
EF - AmeriTek, Inc., Seattle, WA, CFN 3025672

W/L File 97-05  
HFR-PA300/DD  
Device Team/COMSTAT  
SEA-DO R/F

TSP/tsp/dfm: YEE.WL (TRAK 97-31)