

REVIEWER NOTE FOR NR-0375-D-801-B, NR-0375-D-802-S thru -804-S

FROM: Seung J. Lee

04/20/2001

The checklists were not used because the distributor stated in the letter dated 4/19/2001 that the distributor would provide services under its Region I license, with exception that the distributor would no longer distribute new devices and there were no changes to the products since their initial registration or last amendment. Therefore, no safety evaluation was performed.

I checked the background files for all certificates, and found that the following:

For NR-375-D-801-B;

AEG Telefunken Corp., letters dated, 11/22/88, 10/07/88, 08/17/88, 05/11/88, 04/12/88, 07/08/85, 09/26/85, 07/29/83, and 09/15/83, and AEG Telefunken Corp., telefax dated, 12/05/88, and 08/19/88 were transferred to NR-117-D-801-B background files folder.

For NR-375-D-802-S;

IMS's letter dated 07/31/92 was transferred to NR-117-D-802-D background files folder and Lorenz & Engelhardt's application for AEG dated 06/08/90 can be found in NUDOC 9706100017 (see ML003768900).