

# **CPG Sec. 590.300 Direct Reference Authority for Pseudomonas Contamination of Cosmetics Used in the Eye Area**

## **REGULATORY ACTION GUIDANCE:**

The following represents criteria for deciding when direct reference seizure \*requests to the Office of Human and Animal Food Operations (OHAFO) in consultation with the Office of Enforcement and Import Operations (OEIO) and CFSAN) is appropriate:

Any cosmetic product intended for use in the eye area which contains *Pseudomonas aeruginosa*.

## **REMARKS:**

Direct reference seizure recommendations should be accompanied by complete labeling and worksheets. Positive identification using the method found in Chapter 25 of the Bacteriological Analytical Manual (BAM) is necessary to support the charge. Speciate *Pseudomonas* isolates using biochemical tests (BAM, Chapter 25) or appropriate commercial identification kits.

## **SPECIMEN CHARGE:**

The article (was adulterated when introduced into and while in interstate commerce) (is adulterated while held for sale after shipment in interstate commerce) within the meaning of the Act, 21 U.S.C. 361(a), in that it contains a poisonous or deleterious substance, *Pseudomonas aeruginosa*, which may render it injurious to users under such conditions of use as are customary or usual.

\*Material between asterisks is new or revised.\*

Issued: 4/10/91

Revised: 8/96, 5/2005

Updated: 11/29/05