

8-4 FACTS COSMETIC ADVERSE EVENT 4184-5 FORM FDA-461

FACTS Version 4.9.01 - [Maintain Consumer Complaints]

Action Edit Options Navigate Tracing Window Help

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**Product/Labeling**

**Cosmetics**

Cosmetics

Product Code: 53 [ ] [ ] [ ] [ ] Cosmetics OK

**Details**

DOB: [ ] [ ] [ ] [ ] [ ] [ ] Age: [ ] Gender: [ ] Race: [ ]

Application Place: [ ] Reason for Use: [ ] Body Application Site: [ ]

Were Other Products Used on Same Site? [ ]

Directions: [ ]

Were Directions Followed? [ ] How Long Product Used? [ ] How Frequent Product Used? [ ] Reaction Site: [ ]

Was Product Used in an 'Off-label' manner? [ ] Off-Label Manner Description: [ ]

Any Warning Statements? [ ] Warning Statements: [ ]

Any Preexisting Conditions? [ ] Total Duration Time: [ ] Treatment? [ ] Current Status: [ ]

Medical Diagnosis: [ ] Medical Treatment: [ ]

Remarks: [ ]

| Name | Last Time Product Used |
|------|------------------------|
| [ ]  | [ ]                    |
| [ ]  | [ ]                    |
| [ ]  | [ ]                    |
| [ ]  | [ ]                    |

Buttons: Add, Delete, Add, Delete, Up, Down, ?

Record: 1/1 <OSC> <DBG>