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

**Product/Labeling**

**Cosmetics**

- **Product Code:** 13
- **Gender:**
- **Race:**

**Details**

- **DOB:**
- **Age:**

**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?**

**Any Warning Statements?**

**Off-Label Manner Description:**

**Warning Statements:**

**Any Preexisting Conditions?**

**Medical:**

**Diagnosis:**

**Remarks:**

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**Record:** 1/1