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MAUDE Adverse Event Report

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LOCAL HEALTH FOOD STORE EAR CANDLE

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Event Date 12/07/2008

Event Type Injury **Patient Outcome** Hospitalization; Disability

Event Description

Used "ear candle" from health food store. Wax dripped into my ear causing burning & wax blocked my eardrum. Experienced severe pain & impaired hearing. I used this product per package instructions. Defective product caused hot was to enter my ear canal - burning and blockage resulted. Prescription ear drops 2008. Ear flush performed by rn and z-pack antibiotic prescribed five days later. Out pt surgery to remove blockage in the same month. Dose or amount: 1 candle per ear. Frequency: once. Route: dates of use: 2008. (1 time only). Reason for use: clean ears. Event abated after use stopped or dose reduced: no.

Search Alerts/Recalls

New Search | Submit an Adverse Event Report

Type of Device	EAR CANDLE
Manufacturer *(Section D)*	LOCAL HEALTH FOOD STORE
Device Event Key	1339063
MDR Report Key	1276183
Event Key	1217794
Report Number	MW5009478
Device Sequence Number	1
Product Code	JYH

Report Source	Voluntary
Reporter Occupation	Patient
Type of Report	Initial
Report Date	12/30/2008
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	12/30/2008
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	Yes
Device Operator	Lay User/Patient
Was Device Available For Evaluation?	No
Is The Reporter A Health Professional?	No
Was The Report Sent To Manufacturer?	No
Is this a Reprocessed and Reused Single-Use Device?	No
Is the Device an Implant?	No
Is this an Explanted Device?	