

Meyers, Beth

From: Havery, Donald C
Sent: Friday, March 16, 2012 2:58 PM
To: Meyers, Beth
Subject: RE: Brazilian Blowout Adverse Event Response Letters-Please Review
Attachments: Adverse Event Response Letter_Hair Smoothers (3).doc.html

Beth,

Back to you with a minor edit or two. I think your suggestion below is a good one. Thanks for the information, but.....please file a MedWatch report.

Don

From: Meyers, Beth
Sent: Thursday, March 15, 2012 4:10 PM
To: Havery, Donald C
Subject: FW: Brazilian Blowout Adverse Event Response Letters-Please Review

Don,

Here you go. I always feel sorry asking people to file a MedWatch report after they've already gone to the trouble of writing a letter, but that's what we always do. It might be nice if we could say something along the lines of, "The information you have provided is helpful. However, to make sure we have the most complete information possible....," or something along those lines. I don't know if that would be accurate or appropriate, however.

Beth

From: Meyers, Beth
Sent: Wednesday, March 14, 2012 12:50 PM
To: Havery, Donald C
Subject: FW: Brazilian Blowout Adverse Event Response Letters-Please Review

Don,

The incoming letters are quite variable. All report health problems, but not all request action on FDA's part. For this reason, if we want one letter to respond to all, we need to delete all references to action requested.

The content also needs to be up to date, including reference to the Warning Letter and or subsequent review of the company's response.

Do we accept reports from salon professionals in CAERS? If so, I would recommend that we address this near the end of the letter, as indicated in my comments. Do they need to fill out a MedWatch form or report to their nearest district office complaint coordinator? Can we use the information provided directly in their letters? In any case, I think we need to address adverse event reporting one way or another.

Beth

From: Havery, Donald C
Sent: Wednesday, March 14, 2012 9:20 AM
To: Meyers, Beth
Subject: FW: Brazilian Blowout Adverse Event Response Letters-Please Review

Beth,

I asked Wendy to draft a response to the package of letters that came in to Linda last month. Would you please review and edit as needed? I didn't read the incoming letters so you might need to look at them to be sure we are answering the question being asked. Thanks.

Don

From: Good, Wendy
Sent: Wednesday, February 15, 2012 4:45 PM
To: Havery, Donald C
Cc: Meyers, Beth
Subject: Brazilian Blowout Adverse Event Response Letters-Please Review

Don,

Please review the attached response to the submitted letters concerning hair smoothers.

Wendy

From: Havery, Donald C
Sent: Friday, February 10, 2012 10:30 AM
To: Good, Wendy
Subject: Brazilian Blowout letters

A follow up thought on those letters..... Talk with Beth and see if we need to keep copies of the letters or file them in DCS. I'm not sure. Thanks.

Don