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Waterman, Sharon

From: HOLOVACM@cder.fda.gov
Sent: Thursday, July 29, 2004 7:01 AM
To: Jamie.Szturo@sanofi-aventis.com; HOLOVACM@cder.fda.gov
Cc: FRIEDMANB@cder.fda.gov; HARE@cder.fda.gov; JONESM@cder.fda.gov
Subject: Arava

Ms. Szturo,

This was discussed internally and agreed upon that YES, it does fall into "marketing." Please send a letter to the OB staff as detailed below asking us to move it to the active Rx list.

Thank you.

Mary Ann Holovac

-----Original Message-----

From: Jamie.Szturo@aventis.com [mailto:Jamie.Szturo@aventis.com]
Sent: Wednesday, July 28, 2004 2:17 PM
To: HOLOVACM@cder.fda.gov
Cc: FRIEDMANB@cder.fda.gov
Subject: RE: Orange Book Update
Importance: High

-----Original Message-----

From: Szturo, Jamie PH/US
Sent: Tuesday, July 27, 2004 1:09 PM
To: 'Holovac, Mary Ann'
Cc: Friedman, Beverly J
Subject: RE: Orange Book Update

Mary Ann,

This is a "Physician Starter Sample" only - does that fall into 'marketing'?

-----Original Message-----

From: Holovac, Mary Ann [mailto:HOLOVACM@cder.fda.gov]
Sent: Tuesday, July 27, 2004 1:07 PM
To: Szturo, Jamie PH/US; Holovac, Mary Ann
Cc: Friedman, Beverly J
Subject: RE: Orange Book Update

send the OB staff a letter asking us to move it to the Rx section if you are marketing it.

7500 Standish Place
Rockville, MD 20855

Than ks.

-----Original Message-----

From: Jamie.Szturo@aventis.com [mailto:Jamie.Szturo@aventis.com]
Sent: Tuesday, July 27, 2004 2:05 PM
To: HOLOVACM@cder.fda.gov
Cc: FRIEDMANB@cder.fda.gov

Subject: RE: Orange Book Update

Mary Ann,

What do I need to do to have the 100mg moved to active?

-----Original Message-----

From: Holovac, Mary Ann [mailto:HOLOVACM@cder.fda.gov]

Sent: Tuesday, July 27, 2004 12:26 PM

To: Szturo, Jamie PH/US; Holovac, Mary Ann

Cc: Friedman, Beverly J

Subject: RE: Orange Book Update

they are all listed in the Orange Book-the 100mg is on the disc list, the other two potencies on the rx list

-----Original Message-----

From: Jamie.Szturo@aventis.com [mailto:Jamie.Szturo@aventis.com]

Sent: Tuesday, July 27, 2004 12:06 PM

To: holovacm@cder.fda.gov

Cc: friedmanb@cder.fda.gov

Subject: Orange Book Update

Importance: High

Dear Mary Ann,

I am following up with you regarding a phone call I received today from Mrs. Friedman.

I need to confirm that for NDA 20-905 - Arava the following dosages should be listed:

10mg

20mg

100mg

Thank you

Jamie Szturo

Aventis Pharmaceuticals Inc.

US Regulatory CMC - J5-M1540

10236 Marion Park Drive

Kansas City, Mo 64137

816-966-5920

816-966-6794 fax

Nextel 816-564-3560

Jamie.Szturo@aventis.com

Visit RCMC Web: http://draprdrwww.brw.hmrags.com/grams/page_item.asp?

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