

Ruch, Paula

From: Ruch, Paula
Sent: Friday, August 10, 2012 10:36 AM
To: 'adolph.vezza@fda.hhs.gov'
Cc: Welton, Becky (Burns); Banker, Poonam S
Subject: RE: ANDA 202321 Oxymorphone HCl Tablets Labeling Deficiency

Dear Mr. Vezza,

Mallinckrodt submitted our response to the labeling deficiency today.

Thank you,

Paula Ruch
Regulatory Affairs Product Specialist
Covidien
Mallinckrodt Inc.
675 James S. McDonnell Blvd., 30-2
Hazelwood, MO 63042
USA

Tel: 314-654-3187
Fax: 314-654-6496

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From: Ruch, Paula
Sent: Wednesday, August 01, 2012 11:10 AM
To: 'adolph.vezza@fda.hhs.gov'
Cc: Servello, Diane L; Welton, Becky (Burns); Banker, Poonam S
Subject: ANDA 202321 Oxymorphone HCl Tablets Labeling Deficiency

Good morning, Mr. Vezza.

I would like to provide an update on our response to the labeling telephone deficiency issued by your office on July 26, 2012. We are currently in the process of revising our package insert and SPL to address the deficiencies. We expect to be able to respond to the deficiencies in the coming week. We will notify you via e-mail once the submission is transmitted through the electronic gateway.

Thank you,

Paula Ruch
Regulatory Affairs Product Specialist
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