

From: [Margaretten, Nadine](#)
To: [Sweeney, Colleen](#)
Cc: [Rivers, Katie](#); [Steele, Matthew](#)
Subject: RE: STN 125592.0 Information Request
Date: Wednesday, March 09, 2016 3:58:50 PM

Dear Colleen, Merck confirms that the Safety Update Report to be submitted under the MK-8237 BLA will include a list of counties for which MK-8237 is registered, and that it will include all available post-approval safety data worldwide (both serious and non-serious reports) up to the SUR cutoff date of 9-April, 2016. Merck will submit the SUR as an amendment to the BLA, STN 125592/0.

Thank you and best regards,
Nadine

Nadine Margaretten, Ph.D.
Senior Principal Scientist
Therapeutic Area Regulatory Liaison
Global Regulatory Affairs
Rahway 34-B1126
Office: 732-594-0373
FAX: 732-594-5235
Administrative Assistant: Sheryl McFadden

From: Sweeney, Colleen [mailto:Colleen.Sweeney@fda.hhs.gov]
Sent: Wednesday, March 09, 2016 12:58 PM
To: Margaretten, Nadine
Cc: Rivers, Katie; Steele, Matthew
Subject: Re: STN 125592.0 Information Request

Dear Dr. Margaretten:

We have the following request for additional information regarding your BLA:

In Section 1.2 of the submission, on pages 4 and 5 of the Cover Letter, your Safety Update Report Plans indicate that MK-8237 was launched in several European countries as of December 2015, and that a safety update report (SUR) will summarize available postmarketing data (up to 9-Apr-2016). Please clarify that the SUR will list all countries in which MK-8237 is current licensed or registered, and will summarize all available post-approval safety data worldwide.

Please submit the above information as an amendment to STN 125592/0.

Thank you,

*Colleen Sweeney R.N., M.S.
Captain, USPHS
Division of Vaccines & Related Product Applications
Office of Vaccines Research & Review
Center for Biologics Evaluation & Research
US Food & Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002.
Tel: +1 301 796 2640
E-Fax: +1 301 402 0004; Fax: +1 301 827 3075
E. Mail: colleen.sweeney@fda.hhs.gov*

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

Notice: This e-mail message, together with any attachments, contains information of Merck & Co., Inc. (2000 Galloping Hill Road, Kenilworth, New Jersey, USA 07033), and/or its affiliates Direct contact information for affiliates is available at <http://www.merck.com/contact/contacts.html>) that may be confidential, proprietary copyrighted and/or legally privileged. It is intended solely for the use of the individual or entity named on this message. If you are not the intended recipient, and have received this message in error, please notify us immediately by reply e-mail and then delete it from your system.