

From: Khurana, Taruna
Sent: Tuesday, February 28, 2017 2:28 PM
To: 'Margaretten, Nadine'
Cc: Steele, Matthew; Sweeney, Colleen
Subject: RE: Question on SQ-HDM inclusion in UCUM: STN 125592:

Dear Nadine,

We have determined that you should do the following to resolve the issues of adding SQ-HDM to UCUM data and SPL format of label;

Please contact the SPL administrator directly at SPL@FDA.hhs.gov to clarify if UCUM unitage is specifically required for your package insert. The UCUM is administered by the Regnesteif Institute. You may also consider contacting them directly regarding your SQ-HDM unit. You may address these issues post-approval but prior to submission of your final label in SPL format.

Thank you
Taruna

From: Margaretten, Nadine [mailto:nadine_margaretten@merck.com]
Sent: Wednesday, February 15, 2017 7:44 PM
To: Sweeney, Colleen
Cc: Steele, Matthew; Khurana, Taruna
Subject: Question on SQ-HDM inclusion in UCUM: STN 125592:

Dear Colleen, I have a question as follow up to the message from Katie Rivers in April, 2016 (see below). She noted that our request to add "SQ-HDM" as a unit of measure to the Unified Code for Units of Measure (UCUM) data standard is pending review.

Question: Will SQ-HDM be added to the UCUM data standard right after BLA approval, or can it be added now? We cannot SQ-HDM in UCUM at this time. It is needed to create the final SPL labeling post approval.

Thanks if you can assist us with this question.
Best regards, Nadine