

From: Bridgewater, Jennifer
Sent: Wednesday, January 11, 2017 1:34 PM
To: Khurana, Taruna
Cc: Sweeney, Colleen; Steele, Matthew
Subject: RE: House Dust Mite BLA STN 125592 UNII Code

I asked Frank about the fish gelatin codes. My assumption was that the codes were new and had just not been entered into the external database yet. And in fact this is the case. The (b) (4) fish gelatin UNII (b) (4) new. See attached email for more detail.

I now agree that all UNII codes are acceptable and may be transmitted to the Applicant.

Thanks,
Jen

<< Message: RE: House Dust Mite BLA STN 125592 UNII Code >>

From: Khurana, Taruna
Sent: Wednesday, January 11, 2017 12:10 PM
To: Bridgewater, Jennifer
Cc: Sweeney, Colleen; Steele, Matthew
Subject: RE: House Dust Mite BLA STN 125592 UNII Code

Thank you Jenn, I noticed the same as well.
fish gelatin (b) (4). But Frank added in his email that these are based on current labeling requirement according to revised (b) (4) gelatin.

Let us know if you get clarification from Frank or if he provides some link to verify (b) (4). The rest codes are correct.

Taruna

From: Bridgewater, Jennifer
Sent: Wednesday, January 11, 2017 11:45 AM
To: Khurana, Taruna
Cc: Sweeney, Colleen; Steele, Matthew
Subject: RE: House Dust Mite BLA STN 125592 UNII Code

Hello Taruna –

I have searched the UNII code database and a few other sources; and I was able to confirm that all of the UNII codes are correct and consistent across different products EXCEPT for the (b) (4) fish gelatin (b) (4). I am unable to confirm (b) (4) exist at all using any of the search terms. I have asked Frank to clarify this.

Thanks
Jennifer

From: Khurana, Taruna
Sent: Wednesday, January 11, 2017 9:51 AM
To: Bridgewater, Jennifer
Cc: Sweeney, Colleen; Steele, Matthew
Subject: FW: House Dust Mite BLA STN 125592 UNII Code

Hello Jenn,

Please confirm that the following UNII Codes for HDM SLIT formulation are satisfactory and I will convey these to Merck.

Active Ingredients

DERMATOPHAGOIDES PTERONYSSINUS (b) (4)
DERMATOPHAGOIDES FARINAE (b) (4)

Inactive Ingredients

(b) (4) GELATIN, (b) (4) Gelatin (Fish (b) (4))
(b) (4)
MANNITOL (b) (4)
SODIUM HYDROXIDE (b) (4)

Thank you
Taruna

From: FDA-SRS
Sent: Wednesday, January 11, 2017 8:11 AM
To: Bridgewater, Jennifer; UNII_REQUEST; FDA-SRS
Cc: Khurana, Taruna; Sweeney, Colleen; Amugoda, Dammika *; Callahan, Lawrence; Borodina, Yulia
Subject: RE: House Dust Mite BLA STN 125592 UnII Code Request

Hi Everyone,

Sorry for the delay. Here are the UNII's. The gelatin (b) (4) labeling requirements under the current (b) (4)/NF gelatin monograph and the (b) (4)

Regards,

Frank

Active Ingredients

DERMATOPHAGOIDES PTERONYSSINUS
DERMATOPHAGOIDES FARINAE

(b) (4)
(b) (4)

Inactive Ingredients

(b) (4) GELATIN, (b) (4)
(b) (4)

(b) (4)
(b) (4)

Gelatin (Fish (b) (4))

MANNITOL
SODIUM HYDROXIDE

Frank L Switzer, PhD
Chemist, FDA Substance Registration System
WO 32 Rm 2227
10903 New Hampshire Ave.
Silver Spring, MD 20993
Office: (301) 796-8506
Mobile: (240) 401-5897

From: Khurana, Taruna
Sent: Monday, August 15, 2016 12:18 PM
To: CBER SRS
Subject: House Dust Mite BLA STN 125592 UnII Code Request

CBER SRS Team,

Please see below for the list of ingredients for 12 DU House Dust Mite Sublingual Tablet, STN 125592/0 and the attached draft labeling that applicant submitted. Action due date is February 8, 2017. Let me know if you need additional information.

Active Ingredients

Dermatophagoides pteronyssinus
Dermatophagoides farinae

Inactive Ingredients

Gelatin (Fish (b) (4))
(b) (4)
Mannitol
Sodium Hydroxide

Thank you,

Taruna
<< File: Draft PI HDM 125592.pdf >>

Taruna Khurana, Ph.D.
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