



LABELING REVIEW MEMORANDUM

To: The File

Date: July 15, 2021

STN: 125741/0

Submission Type: Original BLA

Applicant: Merck Sharp and Dohme Corp.

Product: Pneumococcal 15-Valent Conjugate Vaccine (Vaxneuvance)

From: Taruna Khurana, PhD
Regulatory Review Branch 1 (RRB1)
Division of Vaccines and Related Product Applications (DVRPA)
Office of Vaccines Research and Review (OVRR)

Tatiana Claro da Silva, PhD
RRB1/DVRPA/OVRR

Through: Jon Daugherty, PhD
RRB1/DVRPA/OVRR

The product labeling submitted in this rolling submission, original BLA, included carton (package) and container (syringe) labels, draft prescribing information (PI) and patient information sheet. The PI incorporates safety and efficacy data in support of the use of Pneumococcal 15-Valent Conjugate Vaccine (Vaxneuvance) for active immunization for the prevention of invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F in adults 18 years of age and older. Vaxneuvance is supplied as one 0.5 mL single-dose prefilled syringe and carton of ten 0.5 mL single-dose prefilled syringes. See the Summary Basis of Regulatory Action memo for detailed description of the submission.

Revisions and information requests regarding the draft labels for the cartons, containers, patient information sheet and PI were communicated to the Applicant, from here on referred as Merck. Merck's responses to CBER's suggested revisions were submitted to STN 125741/0 under multiple amendments.

The principal reviewers of the draft PI were the Committee Chair, the Clinical Review Team, the Product Review Team, the Biostatistics Reviewers, the Advertising and

Promotional Labeling Branch (APLB) Reviewer, the Carton and Container Labeling Reviewer, the Regulatory Project Managers (RPMs), and the supervisors.

Advice and recommendation were also provided by DVRPA and OVRR Immediate Offices of the Directors (IOD).

The following is a list of CBER's labeling-related activities and Merck's labeling-containing amendments submitted to this BLA:

PI and Patient Information Sheet - Related Review Team Meetings:

March 25, 2021

March 29, 2021 (Discussion of the VRC data issues with the division and office management)

March 29, 2021

April 06, 2021

April 12, 2021

April 15, 2021

April 29, 2021 (Meeting with the IOD)

May 13, 2021 (Meeting with the IOD)

May 20, 2021

May 21, 2021 (Meeting with the IOD)

May 25, 2021 (Meeting with the IOD)

June 24, 2021 (Meeting with the IOD)

July 08, 2021

July 13, 2021 (Meeting with the IOD and APLB)

CBER's comments sent to Merck regarding the PI:

June 03, 2021 Information Request #24 (First round of comments and revisions)

June 28, 2021 Information Request #31 (Second round of comments and revisions)

CBER's comments sent to Merck regarding the Patient Information Sheet

June 28, 2021 Information Request #31 (First round of comments and revisions)

July 09, 2021 Information Request #32 (Second round of comments and revisions)

July 13, 2021 Information Request # 32a (Third round of comments and revisions)

Merck's Amendments containing revisions to the PI and Patient Information Sheet:

Merck submitted amendments 37 (June 10, 2021), 44 (July 2, 2021) and 45 (July 14, 2021) to STN 125741/0, in response to CBER's revisions communicated under IR#'s 24, 31, 32, and 32a. Their responses included clean and annotated versions of the PI and Patient Information sheet. The revisions and labeling negotiations were made throughout the PI, including indication statement and

associated text, adverse reactions, tables, product description, nonclinical toxicology, and clinical studies. The draft Patient Information Sheet was also revised considerably to reflect the information and revisions proposed in the draft PI. The clean copy word version of the PI and Patient Information Sheet received on July 14, 2021 under amendment 45 were reviewed and considered the final draft PI and final draft Patient Information Sheet for approval. Merck was notified on July 15, 2021 that CBER considered these two labeling components as the final drafts acceptable for approval.

Carton and Container Label - Related Review Team Meeting:

June 09, 2021

CBER's Carton- and Container-related labeling comments sent to Merck:

June 11, 2021 Information Request #29

June 28, 2021 Information Request #31

Merck's amendments containing revisions to the Carton and Container labels:

Merck submitted to CBER the revised carton (package) and container (syringe) labels in response to CBER's comments provided as listed above. The responses to CBER's suggested revisions regarding the Carton and Container labels were submitted under amendment 42 received on June 17, 2021 and amendment 44, received on July 02, 2021. During the second round of revisions (IR#31), CBER reiterated the importance of inclusion of the age range on the carton, which Merck accepted. In amendment 45 dated July 14, 2021 Merck included carton labels for one single dose and ten single dose carton labels along with the PI and Patient Information Sheet. Merck was notified on July 15, 2021 that CBER considered the draft container label included in amendment 42, received on June 17, 2021 and the draft carton labels included in amendment 45, dated July 14, 2021 as the final draft packaging labels acceptable for approval.

Review of National Drug Codes (NDC):

The review of NDCs for Vaxneuvance were conducted according to the CBER Job Aid JA 900.08: National Drug Code, Bar Code, and Product Identifiers Labeling Review.

NDC assignments for Vaxneuvance individual container

Packaging	NDC Number
One 0.5 mL single-dose prefilled syringe with tip cap	0006-4329-02
Ten 0.5 mL single-dose prefilled syringes with tip caps	0006-4329-03

Verified first segment (NDC labeler code) using

<https://www.fda.gov/industry/structured-product-labeling-resources/ndcnhric-labeler-codes>

The first segment (labeler code) 0006 is correct and appropriately assigned.

The second segments (product code that identifies dosage form) is different and unique for container labels of 0.5 mL dose (-4329-).

The third segments (package code that identifies package sizes and types) are different for each packaging.

As noted in the Carton and Container labels review memo by Daphne Stewart, the labels meet the NDC label requirements (21 CFR 207.35 (3)).

Recommendation:

The discipline reviewers mentioned above have reviewed the relevant labeling documents and found them to be acceptable as Final Draft Labeling for approval. We concur with the reviewers' recommendations. The final versions of the PI, Patient Information Sheet and the Carton and Container labels will be provided to the Office of Communication, Outreach and Development as part of the approval package for web posting.