



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
Silver Spring, MD 20993

MEMORANDUM

From: Gregory G. Gagliano, M.S.
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Date: 2016.08.18 13:47:24 -04'00'

Through: Hoshing W. Chang, Ph.D.
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Date: 2016.08.18 14:53:40 -04'00'

To: Matthew Holman, Ph.D.
Director
Division of Product Science
Office of Science

Subject: Finding that the pending Market Authorization Orders for House of Oliver Twist A/S, SE0002649 and SE0002651 are in a class of actions categorically excluded under 21 CFR 25.35(a)

Background:

On January 19, 2016, House of Oliver Twist A/S submitted a claim for categorical exclusion from environmental assessment under 21 CFR 25.35(a) for the two provisional substantial equivalence (SE) reports that were submitted on March 21, 2011. The two products under section 905(j) for the Federal Food, Drug, and Cosmetic Act (FD&C Act) are listed below:

STN	New Product Name
SE0002649	Oliver Twist Original, chewing tobacco bits
SE0002651	Oliver Twist Multipack, chewing tobacco bits

Environmental Effect Evaluation:

An order authorizing the marketing of a new tobacco product under section 910(a)(2)(B) of the FD&C Act falls within a class of actions that are ordinarily categorically excluded under 21 CFR 25.35(a).