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APPLICATION NUMBER:

205718Orig1s000

ENVIRONMENTAL ASSESSMENT

Helsinn Healthcare SA submitted a claim of categorical exclusion from the requirement to prepare an environmental assessment (EA) for AKYNZEO. AKYNZEO is a fixed dose combination of netupitant, a substance P/neurokinin 1 (NK1) receptor antagonist, and palonosetron, a serotonin subtype 3 (5-HT3) receptor antagonist.

I have reviewed the claim and determined that the application qualifies for a categorical exclusion under 21 CFR 25.31 (b). No extraordinary circumstances are indicated. No further action is required.

Raanan A. Bloom, Ph.D.

OPS/ONDQA/EA Staff

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/s/

RAANAN A BLOOM
07/21/2014