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*APPLICATION NUMBER:*

**205108Orig1s000**

**MEDICAL REVIEW(S)**



## DIVISION OF CARDIOVASCULAR & RENAL PRODUCTS

### *Divisional Memo*

**NDA:** 205108 Sotalol hydrochloride (Sotylize)

**Sponsor:** Arbor Pharmaceuticals

**Review date:** 17 October 2014

**Reviewer:** N. Stockbridge, M.D., Ph.D., HFD-110

**Distribution:** NDA 205108

This is a 505(b)(2) application for an oral solution of sotalol hydrochloride, relying upon the Agency's findings of safety and effectiveness of Betapace. There are primary reviews of CMC (McLamore-Hines; 23 June and 26 September 2014), biopharmaceutics (Suarez; 18 September 2014), microbiology (Riley; 4 February 2014), DMEPA (Olumba; 19 March and 10 April 2014), DMPP (Dowdy; 10 October 2014), OPDP (Shah; 8 October 2014), and 505(b)(2) assessment (Fortney; 2 and 16 October 2014). There is a comprehensive CDTL memo (Srinivasachar; 16 October 2014) with which I am entirely in agreement.

No reviewer has raised an issue of approvability and the CDTL supports approval. Site inspections are complete. Draft labeling has been sent to the sponsor; agreement on labeling is the sole barrier to completing an approval action.

There are no post-marketing commitments or requirements. There is pediatric labeling considered adequate.

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/s/  
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NORMAN L STOCKBRIDGE  
10/17/2014