

Label and Approval History

Drug Name(s)	ZORBTIVE
FDA Application No.	(NDA) 021597
Active Ingredient(s)	SOMATROPIN RECOMBINANT
Company	EMD SERONO

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Label Information

[What information does a label include?](#)

Note: Not all labels are available in electronic format from FDA.

View the [label approved on 12/01/2003 \(PDF\)](#) for NDA no. 021597

- To see older, previously-approved labels, go to the "[Approval History](#)" section of this page. Older labels are for historical information only and should not be used for clinical purposes.

NPS EX. 2080
CFAD v. NPS
IPR2015-01093

Approval History
NDA 021597

Note: Not all reviews are available in electronic format from FDA.
Older labels are for historical information only, and should not be used for clinical purposes.
Approval dates can only be verified from 1984 to the present.

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Action Date	Supplement Number	Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
12/01/2003	000	Approval	Label (PDF) Letter (PDF) Review	
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- There are no Therapeutic Equivalents

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