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Label and Approval History

Drug Name(s)	MAKENA
FDA Application No.	(NDA) 021945
Active Ingredient(s)	HYDROXYPROGESTERONE CAPROATE
Company	LUMARA HEALTH INC

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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 09/16/2013 (PDF) for NDA no. 021945

- 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.

Approval History NDA 021945

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.

Click on a column header to re-sort the table:

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Action Date	Supplement Number	Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
09/16/2013	005	Labeling Revision	Label (PDF) Letter (PDF)	
02/03/2011	000	Approval	Label (PDF) Letter (PDF) Review Summary Review (PDF)	

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#)

- There are no Therapeutic Equivalents

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