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New Drug Application (NDA): 020692
Company: GLAXOSMITHKLINE

- **Medication Guide (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/020692s047lbl.pdf#page=35)**
- **Other Important Information from FDA (http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm108111.htm)**

Products on NDA 020692

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
SEREVENT	SALMETEROL XINAFOATE	EQ 0.05MG BASE/INH	POWDER;INHALATION	Prescription	None	Yes	Yes

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Approval Date(s) and History, Letters, Labels, Reviews for NDA 020692

Original Approvals or Tentative Approvals

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Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Labels, Patient Package Insert
09/19/1997	ORIG-1	Approval	Type 3 - New Dosage Form	STANDARD	**Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/97/020692s000_SereventTOC.**

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Supplements

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Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
07/22/2019	SUPPL-47	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/020692s047lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/020692Orig1s047ltr.pdf)**	
12/21/2018	SUPPL-46	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020692s046lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2018/020692Orig1s046ltr.pdf)**	
09/30/2016	SUPPL-45	Labeling-Container/Carton Labels	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020692s045lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/020692Orig1s045ltr.pdf)**	
06/17/2016	SUPPL-44	Manufacturing (CMC)		Label is not available on this site.
04/14/2014	SUPPL-43	Labeling-Medication Guide, Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/020692s043lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/020692Orig1s043ltr.pdf)**	
08/09/2012	SUPPL-42	REMS-Modified	**Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2012/021077Orig1s049,021254Orig1s019,020692Orig1s042ltr.pdf)**	Label is not available on this site.
08/09/2012	SUPPL-40	Labeling		Label is not available on this site.
06/27/2011	SUPPL-39	REMS-Modified	**Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/021077s047,021254s016,020692s039ltr.pdf)**	Label is not available on this site.

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
05/10/2011	SUPPL-38	REMS-Assessment, REMS-Modified	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021077s046,021254s015,020692s038lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/021077s046,021254s015,020692s038ltr.pdf)**	
12/30/2010	SUPPL-32	Labeling	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/020692s032lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2010/020692s032ltr.pdf)**	
11/18/2010	SUPPL-35	REMS-Proposal	**Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2010/020692s035ltr.pdf)**	Label is not available on this site.
06/25/2010	SUPPL-36	Labeling-Medication Guide, Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/020692s036lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2010/021077s042,021254s013,020692s036ltr.pdf)**	
03/20/2008	SUPPL-31	Labeling	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021254s003,020692s031lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2008/021254s003,020692s031ltr.pdf)**	
02/23/2007	SUPPL-28	Labeling	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/020692s028lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2007/020692s028, 021077s027ltr.pdf)**	
03/02/2006	SUPPL-29	Labeling	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/020692s029lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2006/021077s028,020692s029ltr.pdf)**	

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
09/28/2004	SUPPL-26	Labeling	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label /2004/20236s030,20692s026lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter /2004/21077s022,20236s030,20692s026ltr.pdf)**	
08/11/2003	SUPPL-24	Labeling	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label /2003/20692slr024_serevent_lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter /2003/20692slr024ltr.pdf)** **Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2003 /020692_s024_SEREVENT DISKUS.pdf)**	
05/17/2002	SUPPL-20	Manufacturing (CMC)-Control		Label is not available on this site.
05/15/2002	SUPPL-18	Manufacturing (CMC)		Label is not available on this site.
03/22/2002	SUPPL-16	Efficacy-New Indication	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label /2002/20692s16lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter /2002/20692s016ltr.pdf)**	
10/16/2001	SUPPL-17	Manufacturing (CMC)-Control		Label is not available on this site.
05/17/2001	SUPPL-15	Labeling		Label is not available on this site.
01/19/2001	SUPPL-9	Manufacturing (CMC)-Control		Label is not available on this site.

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
06/29/2000	SUPPL-11	Efficacy-Labeling Change With Clinical Data		Label is not available on this site.
06/15/2000	SUPPL-13	Manufacturing (CMC)-Control		Label is not available on this site.
04/03/2000	SUPPL-12	Manufacturing (CMC)-Control		Label is not available on this site.
07/20/1999	SUPPL-10	Manufacturing (CMC)		Label is not available on this site.
12/03/1998	SUPPL-6	Manufacturing (CMC)-Control		Label is not available on this site.
09/25/1998	SUPPL-2	Efficacy-New Patient Population	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/1998/20692s1-2lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/1998/20692s1-2ltr.pdf)** **Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/98/20692S1,2_Serevent.cfm)**	
09/25/1998	SUPPL-1	Efficacy-New Indication	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/1998/20692s1-2lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/1998/20692s1-2ltr.pdf)** **Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/98/20692S1,2_Serevent.cfm)**	

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05/21/1998	SUPPL-5	Labeling		Label is not available on this site.
03/26/1998	SUPPL-3	Manufacturing (CMC)-Control		Label is not available on this site.
03/18/1998	SUPPL-8	Manufacturing (CMC)-Control		Label is not available on this site.
03/18/1998	SUPPL-4	Manufacturing (CMC)-Control		Label is not available on this site.
03/11/1998	SUPPL-7	Labeling		Label is not available on this site.

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Labels for NDA 020692