

Regulatory Policy Information for the Topical Antiseptic Drug Products

Consumer Hand and Body Wash Antiseptics					
Deliverable Type	Deliverable Description	Mandated Deadline	Date Issued	Additional Information	Next Steps
Proposed Rule	FR Notice of safety and effectiveness of consumer antiseptics; topical antimicrobial drug products for over-the-counter human use; proposed amendment of the tentative final monograph; reopening of administrative record; proposed rule.	12/16/2013	12/17/2013	Proposed rule on consumer hand and body wash drug products	Industry to provide information to fill data gaps to meet GRASE standards
Process	Comment period for tentative final monograph	12/16/2013		Comments for tentative final monograph	Industry to provide information to fill data gaps to meet GRASE standards
Report	Status report taken by FDA with respect to its obligations under the consent decree		6/2014	Status report six-month period December 17, 2013 – May 18, 2014	FDA intends to continue to take necessary steps to complete the tasks set forth in the Consent Decree
Process	End of comment period to submit new data and information for tentative final monograph	6/16/2014		Comments on new data for tentative final monograph	Industry to provide information to fill data gaps to meet GRASE standards
Report	Status report taken by FDA with respect to its obligations under the consent decree		12/2014	Status report six-month period May 19, 2014 – November 19, 2014	FDA intends to continue to take necessary steps to complete the tasks set forth in the Consent Decree
Process	Rebuttal comment period for tentative final monograph	2/17/2015		Rebuttal comments for tentative final monograph	Industry to provide information to fill data gaps to meet GRASE standards
Report	Status report taken by FDA with respect to its obligations under the consent decree		6/2015	Status report six-month period November 20, 2014 – May 20, 2015	FDA intends to continue to take necessary steps to complete the tasks set forth in the Consent Decree
Report	Status report taken by FDA with respect to its obligations under the consent decree		12/2015	Status report six-month period May 21, 2015 – November 21, 2015	FDA intends to continue to take necessary steps to complete the tasks set forth in the Consent Decree
Process	Deferral Request		3/10/2016	Deferral letter (March 10, 2016): Benzalkonium chloride	Industry to provide information to fill data gaps to meet GRASE standards

				Deferral letter (March 10, 2016): Benzethonium chloride	Industry to provide information to fill data gaps to meet GRASE standards
				Deferral letter (March 10, 2016): Chloroxylonol	Industry to provide information to fill data gaps to meet GRASE standards
Report	Status report taken by FDA with respect to its obligations under the consent decree	6/3/2016	6/3/2016	Status report six-month period November 22, 2015 – May 22, 2016	FDA intends to continue to take necessary steps to complete the tasks set forth in the Consent Decree
Final Rule	Final rule on safety and effectiveness of consumer antiseptics; topical antimicrobial drug products for over-the-counter human use.	9/15/2016			
Report	Status report taken by FDA with respect to its obligations under the consent decree	12/2016			

Health Care Antiseptics

Deliverable Type	Deliverable Description	Mandated Deadline	Date Issued	Additional Information	Next Steps
Proposed Rule	FR Notice of safety and effectiveness of health care antiseptics; topical antimicrobial drug products for over-the-counter human use; proposed amendment of the tentative final monograph; reopening of administrative record; proposed rule.	4/30/2015	5/1/2015	Proposed rule on health care antiseptic drug products	Industry to provide information to fill data gaps to meet GRASE standards
Report	Status report taken by FDA with respect to its obligations under the consent decree	6/2015	6/2015	Status report six-month period November 20, 2014 – May 20, 2015	FDA intends to continue to take necessary steps to complete the tasks set forth in the Consent Decree
Process	Comment period for tentative final monograph	10/31/2015	10/31/2015	Comments for tentative final monograph	Industry to provide information to fill data gaps to meet GRASE standards
Report	Status report taken by FDA with respect to its obligations under the consent decree	12/2015	12/2015	Status report six-month period May 21, 2015 – November 21, 2015	FDA intends to continue to take necessary steps to complete the tasks set forth in the Consent Decree
Process	End of comment period to submit new data and information for tentative final monograph	4/30/2016	5/1/2016	Comments on new data for tentative final monograph	Industry to provide information to fill data gaps to meet GRASE standards

Report	Status report taken by FDA with respect to its obligations under the consent decree	6/3/2016	6/3/2016	Status report six-month period November 22, 2015 – May 22, 2016	FDA intends to continue to take necessary steps to complete the tasks set forth in the Consent Decree
Process	Rebuttal comment period for tentative final monograph	6/30/2016		Rebuttal comments for tentative final monograph	Industry to provide information to fill data gaps to meet GRASE standards
Report	Status report taken by FDA with respect to its obligations under the consent decree	12/2016			
Report	Status report taken by FDA with respect to its obligations under the consent decree	6/2017			
Report	Status report taken by FDA with respect to its obligations under the consent decree	12/2017			
Final Rule	Final rule on safety and effectiveness of health care antiseptics; topical antimicrobial drug products for over-the-counter human use.	1/15/2018			

Consumer Hand Rub Antiseptics					
Deliverable Type	Deliverable Description	Mandated Deadline	Date Issued	Additional Information	Next Steps
Proposed Rule	FR Notice of safety and effectiveness of consumer antiseptics; topical antimicrobial drug products for over-the-counter human use; proposed amendment of the tentative final monograph; reopening of administrative record; proposed rule.	6/30/2016	6/30/2016	Proposed rule on consumer hand rub antiseptic drug products	Industry to provide information to fill data gaps to meet GRASE standards
Report	Status report taken by FDA with respect to its obligations under the consent decree	12/2016			
Process	Comment period for tentative final monograph	12/31/2016			

Report	Status report taken by FDA with respect to its obligations under the consent decree	6/2017			
Process	End of comment period to submit new data and information for tentative final monograph	6/30/2017			
Process	Rebuttal comment period for tentative final monograph	8/31/2017			
Report	Status report taken by FDA with respect to its obligations under the consent decree	12/2017			
Report	Status report taken by FDA with respect to its obligations under the consent decree	6/2018			
Report	Status report taken by FDA with respect to its obligations under the consent decree	12/2018			
Final Rule	Final rule on safety and effectiveness of consumer antiseptics; topical antimicrobial drug products for over-the-counter human use.	4/15/2019			