Wrinkle Fillers Approved by the Center for Devices and Radiological Health

U.S. Food & Drug Administration

FDA approval is based on the review of data collected from controlled clinical studies that evaluated the safe and effective use of the wrinkle fillers when injected into specified areas of facial tissue.

More information about the data FDA reviewed to approve each dermal filler exists in the Summary of Safety and Effectiveness Data, which is linked in the additional information listed with each product.

Trade Name (with link to additional information)	**Material**	**Applicant**	**PMA Number**	**Decision Date**	**Approved For:**
BELOTERO BALANCE [1]	Hyaluronic Acid	Merz Pharm aceuticals	P090016	11/14/2011	Injection into facial tissue to smooth wrinkles and folds, especially around the

					nose and mouth (nasolabial folds).
RESTYLANE INJECTABLE GEL [2]	Hyaluronic Acid	Medicis Aesthetics Holdings, Inc	P040024 S051	10/11/2011	Lip augmentation in those over the age of 21 years.
SCULPTRA AESTHETIC [3]	Poly-L-Lactic Acid (PLLA)	Sanofi Aventis U.S.	P030050 S002	7/28/2009	Use in shallow to deep nasolabial fold contour deficiencies and other facial wrinkles.
EVOLENCE COLLAGEN FILLER [4]	Collagen	Colbar Lifescienc l	P070013	6/27/2008	The correction of moderate to deep facial wrinkles and folds (such as nasolabial folds).
PREVELLE SILK [5]	Hyaluronic Acid with Lidocaine	Genzyme Biosurgery	P030032 S007	2/26/2008	Injection into the mid to deep dermis for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds).
RADIESSE 1.3CC AND 0.3CC [6]	Hydroxylapatite	Bioform Medical, Inc	P050037	12/22/2006	Restoration and/or correction

					of the signs of facial fat loss (lipoatrophy) in people with HIV.
RADIESSE 1.3CC AND 0.3CC [7]	Hydroxylapatite	Bioform Medical, Inc	P050052	12/22/2006	Subdermal implantation for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds).
ELEVESS [8]	Hyaluronic Acid with Lidocaine	Anika Therapeutics	P050033	12/20/2006	Use in mid to deep dermis for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds).
ARTEFILL [9]	Polymethyl methacrylate Beads, Collagen and Lidocaine.	Suneva Medical, Inc.	P020012	10/27/2006	Use in facial tissue around the mouth (i.e., nasolabial folds).
JUVEDERM 24HV, JUVEDERM 3 [10]	Hyaluronic Acid	Allergan	P050047	6/2/2006	Use in mid to deep dermis for correction of moderate to severe facial

					wrinkles and folds (such as nasolabial folds).
RESTYLANE INJECTABLE GEL [11]	Hyaluronic Acid	Medicis Aesthetics Holdings, Inc	P040024	3/25/2005	Injection into the mid to deep dermis for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds).
CAPTIQUE INJECTABLE GEL [5]	Hyaluronic Acid	Genzyme Biosurgery	P030032 S002	11/12/2004	Injection into the mid to deep dermis for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds).
SCULPTRA [12]	Poly-L-Lactic Acid (PLLA)	Sanofi Aventis U.S.	P030050	8/3/2004	Restoration and/or correction of the signs of facial fat loss (facial lipoatrophy) in people with Human Immunodeficiency Virus (HIV).
HYLAFORM	Modified	Genzyme	P030032	4/22/2004	Injection

(HYLAN B GEL) [13]	hyaluronic acid derived from a bird (avian) source	Biosurgery			into the mid to deep dermis for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds).
RESTYLANE INJECTABLE GEL [14]	Hyaluronic Acid	Q-med Ab	P020023	12/12/2003	Injection into the mid to deep dermis for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds).
COSMODERM 1 HUMAN-BASED C [15]	Collagen	Inamed Corporation	P800022 S050	3/11/2003	Injection into the superficial papillary dermis for correction of soft tissue contour deficiencies, such as wrinkles and acne scars.
FIBREL [16]	Collagen	Serono Laboratories	P850053	2/26/1988	The correction of depressed cutaneous scars which

					are distendable by manual stretching of the scar borders.
ZYPLAST(R) [17]	Collagen	Collagen Corp.	P800022 S011	6/24/1985	Use in mid to deep dermal tissues for correction of contour deficiencies .
ZYDERM COLLAGEN IMPLANT [17]	Collagen	Allergan	P800022	9/18/1981	Use in the dermis for correction of contour deficiencies of this soft tissue.

SOURCE [18]

Source URL (retrieved on *05/19/2013 - 6:17pm*):
http://www.mdtmag.com/news/2012/06/wrinkle-fillers-approved-center-devices-and-radiological-health

Links:
[1] http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm280839.htm
[2] http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm276637.htm
[3] http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm176124.htm
[4] http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm074035.htm
[5] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm?start_search=1&pmanumber=P030032
[6] http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm077270.htm

[7] http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm077277.htm
[8] http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm077282.htm
[9] http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm077416.htm
[10] http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm078154.htm
[11] http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm078657.htm
[12] http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm080931.htm
[13] http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm081167.htm
[14] http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm082242.htm
[15] http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm082635.htm
[16] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm?start_search=1&pmanumber=P850053
[17] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm?start_search=1&pmanumber=P800022
[18] http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/CosmeticDevices/WrinkleFillers/ucm227749.htm