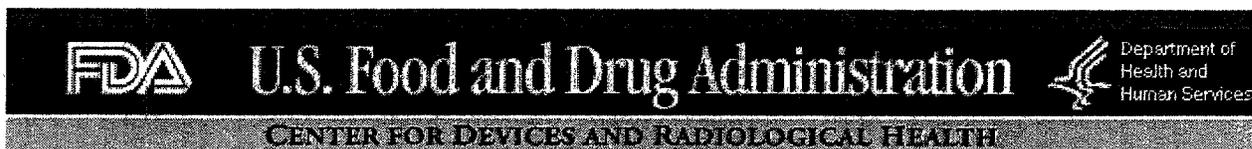


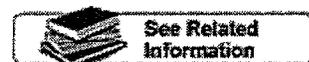
# **ATTACHMENT A**

(Copy of Product Information about RESTYLANE® Injectable Gel)



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## CDRH Consumer Information



## New Device Approval

### Restylane™ Injectable Gel - P020023

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

**Product Name:** Restylane™ Injectable Gel

**Applicant:** Q-Med Scandinavia, Inc.

**Address:** 2325 Dulles Corner Boulevard, Suite 500, Herndon, VA 20171

**Approval Date:** December 12, 2003

**Approval Letter:** <http://www.fda.gov/cdrh/pdf2/P020023a.pdf>

**What is it?** Restylane™ is a transparent hyaluronic acid gel that is injected into facial tissue to smooth wrinkles and folds, especially around the nose and mouth (nasolabial folds). Hyaluronic acid is a substance that is produced naturally by the body.

**How does it work?** Restylane™ works by temporarily adding volume to facial tissue. The effect lasts for about 6 months.

**When is it used?** Restylane™ is injected by a doctor into areas of facial tissue where moderate to severe facial wrinkles and folds occur.

**What will it accomplish?** Restylane™ will help smooth moderate to severe facial wrinkles and folds. In a clinical study most patients needed one injection to achieve optimal wrinkle smoothing; about one-third of patients needed more than one injection to get a satisfactory result. The smoothing effect lasted about six months.

Side effects of Restylane™ include:

- bruising,
- redness,

- swelling,
- pain,
- tenderness, and
- itching.

**When should it not be used?**

Restylane™ should not be used in patients who have:

- severe allergies marked by a history of anaphylaxis (hypersensitivity to the ingestion or injection of a drug or protein),
- multiple severe allergies,
- severe allergies to gram-positive bacterial proteins,

Restylane™ should not be used for:

- breast augmentation,
- implantation into bone, tendon, ligament, or muscle, or
- implantation into blood vessels, because it may obstruct blood flow.

**Additional information:**

Summary of Safety and Effectiveness and labeling will be available at:  
<http://www.fda.gov/cdrh/pdf2/p020023.html>

Other:

- 2003 FDA talk paper “FDA Approves New Product for Facial Wrinkles”:  
<http://www.fda.gov/bbs/topics/ANSWERS/2003/ANS01271.html>

Updated January 20, 2004

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## ***FDA Talk Paper***

T03-85  
December 12, 2003

Media Inquiries: 301-827-6242  
Consumer Inquiries: 888-INFO-FDA

### **FDA Approves New Product for Facial Wrinkles**

The Food and Drug Administration (FDA) today approved an injectable gel to treat facial wrinkles.

Studies conducted by the manufacturer showed that the device, Restylane, is safe and effective for filling moderate to severe wrinkles around the nose and mouth. Most patients needed one injection to get optimal correction; about one-third of patients needed more than one injection to get a satisfactory result. The effect lasted about six months.

Restylane is made with hyaluronic acid. Two other injectable products are approved by FDA for treating wrinkles. Collagen injections are approved for correcting soft tissue deficiencies such as wrinkles and acne scars, and botulinum toxin is approved for treating frown lines between the eyebrows. Other treatments for wrinkles include topical creams, chemical peels and laser and electro-surgical resurfacing.

FDA's approval is based on a review of the clinical studies conducted by the manufacturer and on the recommendation of the General and Plastic Surgery Devices Panel of FDA's Medical Devices Advisory Committee.

In the pivotal study, conducted at six medical centers in the United States, 138 patients with naso-labial folds were injected with Restylane on one side of the face and Zyplast, a bovine collagen product, on the other side of the face. Most of the patients were caucasian women who did not smoke and had minimal previous sun exposure.

The results showed that, six months after treatment, the effects of Restylane and Zyplast as wrinkle fillers were comparable.

As reported by patients within 14 days following the first treatment, the Restylane treated side had a lower incidence of severe redness (5.1% vs. 5.8) and an increased incidence of severe bruising (3.6% vs. 0.7%), severe swelling (3.6% vs. 1.4%), severe pain (3.6% vs. 1.4%), and severe tenderness (2.9% vs. 1.4%) compared with the Zyplast treated side. These incidents were lower with follow up injections for both products.

There was limited data in the study on the safety of Restylane in non-caucasians. The firm, Q-Med AB of Sweden, has agreed to conduct a post approval study in people of color to determine the product's safety for this population. The firm will also provide training to physicians on the correct use of the device.

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