SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I. GENERAL INFORMATION

Device Generic Name: Injectable Dermal Filler

Device Trade Name: JUVÉDERM™

Applicant's Name and Address: Inamed Corporation
5540 Ekwill Street
Santa Barbara, California 93111

Date(s) of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P050047

Date of Notice of Approval to Applicant: June 2, 2006

II. INDICATIONS FOR USE

JUVÉDERM 30, JUVÉDERM 24HV and JUVÉDERM 30HV are injectable gels indicated for injection into the mid to deep dermis for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds).

III. CONTRAINDICATIONS

JUVÉDERM is contraindicated for patients with severe allergies manifested by a history of anaphylaxis or history or presence of multiple severe allergies.

JUVÉDERM contains trace amounts of gram positive bacterial proteins and is contraindicated for patients with a history of allergies to such material.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the JUVÉDERM labeling.

V. DEVICE DESCRIPTION

JUVÉDERM injectable gel is a sterile, biodegradable, non-pyrogenic, viscoelastic, clear, colorless, homogenized gel implant. JUVÉDERM consists of crosslinked hyaluronic acid (HA) formulated to a concentration of 22-26 mg/mL, suspended in a physiological buffer. HA is a naturally occurring polysaccharide of the extracellular matrix in human tissues, including skin. The HA in JUVÉDERM is produced by *Streptococcus equi* bacteria.

The HA used in JUVÉDERM has a molecular weight of approximately 2.5 million Daltons and is crosslinked by adding a minimum amount of BDDE (1,4-butanediol

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Exhibit 1074

diglycidyl ether) to form a 3-dimensional HA gel. The chemical stabilizing (crosslinking) process does not change the polyanionic character of the polysaccharide chain.

JUVÉDERM is available in three formulations (30, 24HV and 30HV) and is supplied in pre-filled disposable syringes. Juvederm 30 HV is a more highly crosslinked robust formulation, injected using a 27G needle for volumizing and correction of deeper folds and wrinkles. Juvederm 24HV is a highly crosslinked formulation that can be injected using a 30 G needle for more versatility in contouring and volumizing of facial wrinkles and folds. Juvederm 30 is a highly crosslinked formulation, injected using a 27G needle, for subtle correction of facial wrinkles and folds. Each syringe contains 0.8 mL of JUVÉDERM gel implant. The syringe is equipped with a Luer lock adaptor, a plunger rod with a latex free stopper, a tip cap and a backstop. Each syringe bears a label with the name of the product, lot number, expiration date, volume, and sterility information. Each Juvéderm filled syringe is packaged in a protective pouch and then placed into a cardboard labeled box along with sterile disposable standard 27G and/or 30G sterile needles, Directions for Use, and product labels.

VI. ALTERNATIVE PRACTICES OR PROCEDURES

Treatment of photo-damaged skin, with its associated wrinkling and changes in texture and pigmentation, is often accomplished by use of topical creams (e.g. retinoids), chemical peeling procedures or laser resurfacing. Deeper wrinkles, folds, scars, and other depressed lesions are often treated with surgery (e.g. rhytidectomy), Botox® Cosmetic injections, or by implantation of dermal filler substances (e.g. injection of collagen, other hyaluronic acid gels, or autologous fat). In these cases, correction of the depression is the goal of therapy.

VII. MARKETING HISTORY

Upon CE marking in 2000, Corneal first introduced a family of non-animal hyaluronate gel implants in Europe under the trade names of JUVÉDERM ® and Hydrafill®. The JUVÉDERM family of products was later introduced in Canada in 2002.

In 2004, Corneal and Inamed formed a partnership for the clinical development and commercial distribution of JUVÉDERM hyaluronate gel implants in Canada, Australia and the United States and in Europe under the trade name Hydrafill.

The device has not been withdrawn from marketing in any country for any reason related to the safety or effectiveness of the device.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

In a U.S. Investigational Device Exemptions (IDE) study 439 subjects at 11 centers were randomized to one of three cohorts (JUVÉDERM 30, JUVÉDERM 24HV or JUVÉDERM 30HV) and received JUVÉDERM injections in one side of the face (nasolabial fold [NLF]) and injections of an injectable bovine collagen (Control) in the

other side of the face. Subjects recorded their observations of treatment responses for each side of the face in pre-printed diaries during the first 14 days following each treatment. The diaries included check boxes for commonly expected treatment responses, e.g. redness, swelling, pain, bruising, and itching, at the injection/application sites. A diary was completed for each initial and subsequent "touch up" treatment. It should be noted that the study subjects were required to record the presence and level of severity for each observed treatment response as "Mild," "Moderate," "Severe," or "None." A summary of the maximum severity and duration of the subject observations is presented in Tables 1 through 6 on the following pages.

Injection site responses reported by greater than 1% but less than 5% of subjects and not noted in the following tables were skin peeling and wrinkling in the JUVÉDERM 30 cohort; skin peeling and dryness in the JUVÉDERM 24HV cohort; and skin peeling and tingling in the JUVÉDERM 30HV cohort.

Table 1 – JUVÉDERM 30 vs. Control
Injection Site Responses by Maximum Severity
Occurring in >5% of Treated Subjects
(Number / % of Subject NLFs)

Injection Site Responses	TOTALS		JUVÉDERM 30 (N*=149 NLFS)			Control** (N*=149 NLFs)		
	JUVÉDERM 30 n‡ %	Control** n‡ %	Mild n‡ %	Mod† n‡ %	Severe n‡ %	Mild n‡ %	Mod† n‡ %	Severe n‡ %
Firmness	136 91%	132 89%	62 42%	66 44%	8 5%	60 40%	63 42%	9 6%
Redness	134 90%	132 89%	73 49%	44 30%	17 11%	63 42%	54 36%	15 10%
Swelling	132 89%	128 86%	65 44%	58 39%	9 6%	81 54%	43 29%	4 3%
Pain/Tenderness	129 87%	128 86%	74 50%	45 30%	10 7%	91 61%	33 22%	4 3%
Lumps/Bumps	123 83%	122 82%	65 44%	49 33%	9 6%	64 43%	50 34%	8 5%
Bruising	91 61%	79 53%	49 33%	27 18%	15 10%	51 34%	25 17%	3 2%
Discoloration	46 31%	43 29%	36 24%	7 5%	3 2%	37 25%	5 3%	1 1%
Itching	42 28%	52 35%	31 21%	10 7%	1 1%	38 26%	11 7%	3 2%

* Number of subject NLFs treated with the respective device
**A commercially available injectable bovine collagen
† Mod = Moderate
‡Number of subject NLFs with each specific injection site response

Table 2 – JUVÉDERM 24HV vs. Control
Injection Site Responses by Maximum Severity
Occurring in >5% of Treated Subjects
(Number / % of Subject NLFs)

Injection Site Responses	TOTALS		JUVÉDERM 24HV (N*=146 NLFS)			Control** (N*=146 NLFs)		
	JUVÉDERM 24HV n‡ %	Control** n‡ %	Mild n‡ %	Mod† n‡ %	Severe n‡ %	Mild n‡ %	Mod† n‡ %	Severe n‡ %
Redness	136 93%	130 89%	72 49%	48 33%	16 11%	69 47%	45 31%	16 11%
Pain/Tenderness	131 90%	128 88%	74 51%	45 31%	12 8%	87 60%	34 23%	7 5%
Firmness	129 88%	127 87%	66 45%	53 36%	10 7%	60 41%	56 38%	11 8%
Swelling	125 86%	122 84%	60 41%	54 37%	11 8%	77 53%	37 25%	8 5%
Lumps/Bumps	115 79%	122 84%	61 42%	45 31%	9 6%	66 45%	42 29%	14 10%
Bruising	86 59%	80 55%	43 29%	29 20%	14 10%	47 32%	27 18%	6 4%
Itching	52 36%	53 36%	42 29%	5 3%	5 3%	43 29%	7 5%	3 2%
Discoloration	48 33%	49 34%	31 21%	11 8%	6 4%	31 21%	15 10%	3 2%

*Number of subject NLFs treated with the respective device
**A commercially available injectable bovine collagen
† Mod = Moderate
‡Number of subject NLFs with each specific injection site response

Table 3 – JUVÉDERM 30HV vs. Control
Injection Site Responses by Maximum Severity
Occurring in >5% of Treated Subjects
(Number / % of Subject NLFs)

Injection Site Responses	TOTALS		JUVÉDERM 30HV (N*=144 NLFS)			Control** (N*=144 NLFs)		
	JUVÉDERM 30HV n‡ %	Control** n‡ %	Mild n‡ %	Mod† n‡ %	Severe n‡ %	Mild n‡ %	Mod† n‡ %	Severe n‡ %
Redness	129 90%	128 89%	61 42%	61 42%	7 5%	71 49%	42 29%	15 10%
Pain/Tenderness	129 90%	123 85%	68 47%	46 32%	15 10%	86 60%	32 22%	5 3%
Firmness	127 88%	122 85%	59 41%	53 37%	15 10%	62 43%	51 35%	9 6%
Swelling	124 86%	121 84%	61 42%	50 35%	13 9%	71 49%	41 28%	9 6%
Lumps/Bumps	120 83%	113 78%	57 40%	53 37%	10 7%	66 46%	40 28%	7 5%
Bruising	87 60%	69 48%	47 33%	33 23%	7 5%	38 26%	25 17%	6 4%
Itching	49 34%	51 35%	38 26%	9 6%	2 1%	39 27%	9 6%	3 2%
Discoloration	49 34%	43 30%	29 20%	15 10%	5 3%	31 22%	9 6%	3 2%

* Number of subject NLFs treated with the respective device
**A commercially available injectable bovine collagen
† Mod = Moderate
‡Number of subject NLFs with each specific injection site response

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