

# MonoSol Rx, LLC

6560 MELTON ROAD, PORTAGE, IN 46368 (219) 762-8112 FAX: (219) 764-4785 [www.monosolrx.com](http://www.monosolrx.com)



0285 7 NOV 13 A11:14

November 12, 2007

OVERNIGHT COURIER (11/12/07)

Division of Dockets Management  
Food and Drug Administration (HFA-305)  
Department of Health and Human Services  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**Withdrawal of Citizen Petition 2006P-0305**  
**Loperamide Orally Dissolving Strips, 2 mg**

Dear Sir or Madam:

The undersigned submitted the above-referenced petition on August 2, 2006, under Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act, and in accordance with 21 CFR 10.30, requesting the Commissioner of Food and Drug to declare that the drug product, Loperamide Hydrochloride Orally Dissolving Strips, 2 mg, is suitable for consideration in an abbreviated new drug application (ANDA). At this time, we request that this petition be withdrawn without prejudice for refiling.

Respectfully submitted,

Pradeep Sanghvi, Ph.D.  
MonoSol Rx, LLC  
6560 Melton Road  
Portage, IN 46368

cc: Craig Kiester (OGD)

2006P-0305

WDL1

# ***MonoSol Rx, LLC***

6560 MELTON ROAD, PORTAGE, IN 46368 (219) 762-8112 FAX: (219) 764-4785 [www.monosolrx.com](http://www.monosolrx.com)



0286 7 NOV 13 A11:14

November 12, 2007

**OVERNIGHT COURIER (11/12/07)**

Division of Dockets Management  
Food and Drug Administration (HFA-305)  
Department of Health and Human Services  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**Withdrawal of Citizen Petition 2006P-0305**  
**Loperamide Orally Dissolving Strips, 2 mg**

Dear Sir or Madam:

The undersigned submitted the above-referenced petition on August 2, 2006, under Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act, and in accordance with 21 CFR 10.30, requesting the Commissioner of Food and Drug to declare that the drug product, Loperamide Hydrochloride Orally Dissolving Strips, 2 mg, is suitable for consideration in an abbreviated new drug application (ANDA). At this time, we request that this petition be withdrawn without prejudice for refiling.

Respectfully submitted,

Pradeep Sanghvi, Ph.D.  
MonoSol Rx, LLC  
6560 Melton Road  
Portage, IN 46368

cc: Craig Kiester (OGD)

# MonoSol Rx, LLC



6560 MELTON ROAD, PORTAGE, IN 46368 (219) 762-8112 FAX: (219) 764-4785 [www.monosolrx.com](http://www.monosolrx.com)

0287 7 NOV 13 AM 11:14

November 12, 2007

OVERNIGHT COURIER (11/12/07)

Division of Dockets Management  
Food and Drug Administration (HFA-305)  
Department of Health and Human Services  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**Withdrawal of Citizen Petition 2006P-0305**  
**Loperamide Orally Dissolving Strips, 2 mg**

Dear Sir or Madam:

The undersigned submitted the above-referenced petition on August 2, 2006, under Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act, and in accordance with 21 CFR 10.30, requesting the Commissioner of Food and Drug to declare that the drug product, Loperamide Hydrochloride Orally Dissolving Strips, 2 mg, is suitable for consideration in an abbreviated new drug application (ANDA). At this time, we request that this petition be withdrawn without prejudice for refiling.

Respectfully submitted,

Pradeep Sanghvi, Ph.D.  
Monosol Rx, LLC  
6560 Melton Road  
Portage, IN 46368

cc: Craig Kiester (OGD)

# MonoSol Rx, LLC



6560 MELTON ROAD, PORTAGE, IN 46368 (219) 762-8112 FAX: (219) 764-4785 [www.monosolrx.com](http://www.monosolrx.com)

0288 7 NOV 13 11:14

November 12, 2007

OVERNIGHT COURIER (11/12/07)

Division of Dockets Management  
Food and Drug Administration (HFA-305)  
Department of Health and Human Services  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**Withdrawal of Citizen Petition 2006P-0305**  
**Loperamide Orally Dissolving Strips, 2 mg**

Dear Sir or Madam:

The undersigned submitted the above-referenced petition on August 2, 2006, under Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act, and in accordance with 21 CFR 10.30, requesting the Commissioner of Food and Drug to declare that the drug product, Loperamide Hydrochloride Orally Dissolving Strips, 2 mg, is suitable for consideration in an abbreviated new drug application (ANDA). At this time, we request that this petition be withdrawn without prejudice for refiling.

Respectfully submitted,

Pradeep Sanghvi, Ph.D.  
MonoSol Rx, LLC  
6560 Melton Road  
Portage, IN 46368

cc: Craig Kiester (OGD)