

**MEMORANDUM**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH**

**PID#:** A060093-D050371

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**THROUGH:** Solomon Iyasu, M.D., M.P.H., Director  
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**TO:** M. Dianne Murphy, MD  
Director, Office of Pediatric Therapeutics (OPT), OIASI  
Office of the Commissioner

CDR Lisa L. Mathis, USPHS M.D.,  
OND Associate Director  
Pediatric and Maternal Health Team  
Office of New Drugs

**SUBJECT:** Amaryl<sup>®</sup> (glimepiride); NDA 20-496/S-015  
One Year Post-Pediatric Exclusivity Postmarketing Adverse Event Review:  
Drug Utilization Data  
Pediatric Exclusivity Grant Date: June 9, 2005

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**\*\*This document contains proprietary drug use data obtained by FDA under contract. The drug use data/information cannot be released to the public/non-FDA personnel without contractor approval obtained through the FDA/CDER Office of Surveillance and Epidemiology.\*\***

**EXECUTIVE SUMMARY**

This consult examines drug utilization patterns for Amaryl<sup>®</sup> (glimepiride) in the pediatric population (ages 0-16 years), with primary focus on patterns of use one year before and one year following the granting of Pediatric Exclusivity on June 9, 2005. Amaryl<sup>®</sup> (glimepiride) is an oral sulfonylurea used to lower blood-glucose levels.

Proprietary drug use databases licensed by FDA were used to conduct this analysis. The IMS Health, IMS National Sales Perspectives<sup>™</sup> was used to determine the various retail and non-retail channels of distribution. Indications for outpatient use were measured by Verispan's Physician Drug and Diagnosis Audit, while retail prescriptions, patient counts and demographics were measured by Verispan's Vector One<sup>®</sup>: National (VONA) and Total Patient Tracker (TPT). We examined outpatient drug use patterns for

Amaryl<sup>®</sup> (glimepiride) and other anti-hyperglycemic agents, including glipizide, glyburide, glyburide micronized, metformin, as well as glipizide/metformin and glyburide/metformin for the three one-year periods from July 1, 2003 through June 30, 2006.

Total dispensed prescriptions for the selected seven anti-hyperglycemic agents increased by nearly 8% from 73.6 million prescriptions during the pre-exclusivity period (July 2004 – June 2005) to almost 79.4 million prescriptions during the post-exclusivity period (July 2005 to June 2006). Amaryl<sup>®</sup> (glimepiride) was the fourth most commonly dispensed product out of these seven anti-hyperglycemic agents and accounted for approximately 9% of the market share in each of the three one-year time periods. The overall number of prescriptions dispensed for Amaryl<sup>®</sup> increased by 7% from 6.7 million prescriptions during the pre-exclusivity period to 7.2 million prescriptions during the post-exclusivity period.

The share of dispensed prescriptions to the pediatric age group represented less than 1% of the total dispensed prescriptions for Amaryl<sup>®</sup> (glimepiride) during all three one-year time periods. In the pediatric population, there was a decreased of nearly 29% from approximately 5,890 prescriptions to approximately 4,210 prescriptions during this time period.

The number of pediatric patients receiving a prescription for Amaryl<sup>®</sup> decreased from approximately 1,901 patients during the pre-exclusivity period to approximately 904 patients during the post-exclusivity period. Similar to dispensed prescription data, pediatric patients accounted for less than 1% of all patients during the entire study period.

General Practitioners and Internal Medicine specialties were the most frequent prescribers of Amaryl<sup>®</sup> and together accounted for nearly 75% of all dispensed prescriptions during the entire study period.

The indication for use most frequently linked to Amaryl<sup>®</sup> in adults during office-based visits was “Diabetes Mellitus Uncomplicated” (ICD-9 250.0). No visit for pediatric patients during which Amaryl<sup>®</sup> was mentioned was recorded during the study period.

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## INTRODUCTION

On January 4, 2002, Congress enacted the Best Pharmaceuticals for Children Act (BPCA) to improve the safety and efficacy of pharmaceuticals for children. Section 17 of that Act requires the reporting of adverse events associated with the use of a drug in children during the one year following the date on which the drug received marketing exclusivity. In support of this mandate, the FDA is required to provide a report to the Pediatric Advisory Committee on the drug utilization patterns and adverse events associated with the use of the drug on a quarterly basis. This review is in addition to the routine post-marketing safety surveillance activities the FDA performs for all marketed drugs.

Approved on November 30, 1995, Amaryl<sup>®</sup> (glimepiride; NDA 20-496) is an oral sulfonylurea agent used to lower blood-glucose levels. Amaryl<sup>®</sup> is indicated as an adjunct to diet and exercise to lower blood glucose levels in patients with noninsulin-dependent (Type 2) diabetes mellitus (NIDDM) whose hyperglycemia cannot be controlled by diet and exercise alone. On February 24, 1999, Amaryl<sup>®</sup> was approved for concomitant use with metformin under NDA 20-496/S-002 when diet, exercise, and Amaryl<sup>®</sup> or metformin alone do not result in adequate glycemic control.

The Pediatric Exclusivity Board of the FDA granted pediatric exclusivity for Amaryl<sup>®</sup> (glimepiride NDA 20-496) on June 9, 2005. On November 28, 2005, Amaryl<sup>®</sup> was approved under NDA 20-496/S-015 for

use in the pediatric population based on an active-controlled, single-blind, 24-week trial involving 272 pediatric patients, ages 8 to 17 years old with Type 2 diabetes.<sup>1</sup>

This review describes outpatient drug use patterns for Amaryl<sup>®</sup> (glimepiride) compared to other anti-hyperglycemic agents for the three one-year periods from July 1, 2003 through June 30, 2006. Proprietary drug use databases licensed by the FDA were used to conduct this analysis.

## METHODS

IMS Health, IMS National Sales Perspectives<sup>™</sup> data (see Appendix) were used to determine the setting in which Amaryl<sup>®</sup> (glimepiride) is sold. Sales of this product by number of vials/cartridges sold from the manufacturer into the various retail and non-retail channels of distribution were analyzed for three years, from year 2003 through year 2005. From these data, it was clear that this product is distributed to the outpatient setting (chain, independent, food store, and mail order pharmacies), which accounted for greater than 91% of the total number of tablets sold in each of the three one-year periods in this analysis.<sup>2</sup> Retail pharmacies (chain, independent, and food stores with pharmacies) accounted for almost 71% of overall sales, where as mail order pharmacies accounted for almost 21% of sales during year 2005.

Because the bulk of drug product sales of Amaryl<sup>®</sup> for this time period were to outpatient retail settings, we examined the utilization patterns for Amaryl<sup>®</sup> focusing on the outpatient setting only. We also examined other selected anti-hyperglycemic agents, including glipizide, glyburide, glyburide micronized, metformin as well as glipizide/metformin and glyburide/metformin.

Outpatient use and patient demographics were measured with the following data sources from Verispan, LLC: Vector One<sup>®</sup>: National (VONA), Total Patient Tracker (TPT); indications for use were obtained from the Physician's Drug and Diagnosis Audit (see Appendix). Estimates of the number of drug mentions during office-based physician visits, the number of dispensed prescriptions by retail pharmacies and the number of patients<sup>3</sup> who were dispensed Amaryl<sup>®</sup> in the retail settings, were obtained. Outpatient drug utilization patterns were examined for the 3-year period from July 1, 2003 through June 30, 2006.

## RESULTS

### I. Dispensed Prescriptions

There was a significant increase in the volume of prescriptions dispensed for the selected anti-hyperglycemic agents (glimeperide, glipizide, glyburide, glyburide micronized, metformin, glipizide/metformin and glyburide/metformin) over the 3 years of this analysis (Table 1). During the pre-exclusivity period (July 2004 to June 2005), 73.6 million prescriptions (95% CI: 73,580,578 - 73,620,592) were dispensed by retail pharmacies in the U.S. for these selected anti-hyperglycemic agents. During the post-exclusivity period (July 2005 to June 2006), almost 79.4 million prescriptions (95% CI: 79,377,630 - 79,419,206) were dispensed. This represented a 7.9% increase from the pre-exclusivity period to the post-exclusivity period. Of these seven agents, prescriptions dispensed for the single-ingredient products, metformin, glipizide and glimepiride continued to increase over the 3-year period. Dispensed prescriptions for glyburide remained fairly steady at 8.9 million during this entire time period. In terms of market share, the single ingredient metformin products had the highest market share among

<sup>1</sup> Amaryl<sup>®</sup> NDA 20-496/S-015 approval letter and product labeling dated November 28, 2005.

<sup>2</sup> IMS Health, IMS National Sales Perspectives<sup>™</sup>, Data extracted 8-2006, File: 0608amar.dvr

<sup>3</sup> Note that data concerning the total number of patients based on Verispan's Total Patient Tracker may not be summed due to aging of patients during the study period.

these selected anti-hyperglycemic agents and their market share increased from 45.3% in the 12-month period ending June 2004 to 51.0% for the 12-month period ending June 2006. In contrast, the number of dispensed prescriptions for the combination metformin/sulfonylurea products as well as micronized glyburide decreased over the 3-year time period.

**Table 1: Total Number of Prescriptions Dispensed by Retail Pharmacies for Selected Anti-Hyperglycemic Agents During July 1, 2003 through June 30, 2006 (mail order pharmacies not included)**

	July 2003 - June 2004		July 2004 - June 2005		July 2005 - June 2006	
	TRxs	Share %	TRxs	Share %	TRxs	Share %
<b>TOTAL MARKET</b>	70,201,015	100.0%	73,600,585	100.0%	79,398,418	100.0%
metformin hcl	31,794,168	45.3%	35,098,252	47.7%	40,480,130	51.0%
glipizide	15,188,371	21.6%	15,576,825	21.2%	15,917,769	20.0%
glyburide	8,931,867	12.7%	8,856,863	12.0%	8,927,925	11.2%
<b>glimepiride</b>	<b>6,459,540</b>	<b>9.2%</b>	<b>6,728,550</b>	<b>9.1%</b>	<b>7,196,239</b>	<b>9.1%</b>
glyburide/metformin hcl	6,194,450	8.8%	5,891,629	8.0%	5,568,894	7.0%
glyburide micronized	1,169,287	1.7%	1,000,308	1.4%	893,855	1.1%
glipizide/metformin hcl	463,332	0.7%	448,158	0.6%	413,606	0.5%

Verispan, LLC, Vector One® National (VONA) Data extracted 9-21-06; File: A060093 9-21-06 Amaryl TRxAge Unrounded.qry

\*Subtotals may not sum exactly, due to rounding error.

Amaryl® (glimepiride) was the fourth most commonly dispensed product out of these seven anti-hyperglycemic agents and accounted for approximately 9% of the market share in each of the three one-year time periods. Prescriptions dispensed for Amaryl® increased by 7% from 6.7 million prescriptions (95% CI: 6,722,578 - 6,734,522) during the pre-exclusivity period (July 2004 – June 2005) to 7.2 million prescriptions (95% CI: 7,190,060 - 7,202,418) during the post-exclusivity period (July 2005 – June 2006) (Table 1).

## **II. Patient Demographics**

Retail prescriptions for Amaryl® (glimepiride) dispensed to the pediatric population (ages 0 – 16 years) decreased by nearly 29%, from approximately 5,890 prescriptions (95% CI: 5,720 – 6,060) dispensed during the pre-exclusivity period (July 2004 – June 2005) to approximately 4,210 prescriptions (95% CI: 4,066 – 4,354) dispensed during the post-exclusivity period (July 2005 – June 2006) (Table 2). The share of dispensed prescriptions to the pediatric age group represented less than 1% of the total dispensed prescriptions for Amaryl® during all three one-year time periods. Prescriptions dispensed to adults (age 17 years and above) increased by approximately 7%, from 6.6 millions dispensed prescriptions (95% CI: 6,658,062 - 6,669,948) during the pre-exclusivity period to 7.1 million dispensed prescriptions (95% CI: 7,146,123 – 7,158,441) during the post-exclusivity period.

**Table 2. Total Number of Prescriptions Dispensed by Retail Pharmacies for Selected Anti-Hyperglycemic Agents by Patient Age, During July 1, 2003 through June 30, 2006 (mail order pharmacies not included)**

	July 2003 - June 2004		July 2004 - June 2005		July 2005 - June 2006	
	TRxs	Share %	TRxs	Share %	TRxs	Share %
<b>TOTAL MARKET</b>	<b>70,201,015</b>	<b>100.0%</b>	<b>73,600,585</b>	<b>100.0%</b>	<b>79,398,418</b>	<b>100.0%</b>
<b>metformin hcl</b>	31,794,168	45.3%	35,098,252	47.7%	40,480,130	51.0%
<b>0-16</b>	117,717	0.4%	141,093	0.4%	151,592	0.4%
<b>17+</b>	31,512,884	99.1%	34,723,535	98.9%	40,125,864	99.1%
<b>UNSPEC.</b>	163,567	0.5%	233,624	0.7%	202,674	0.5%
<b>glipizide</b>	15,188,371	21.6%	15,576,825	21.2%	15,917,769	20.0%
<b>0-16</b>	34,614	0.2%	36,117	0.2%	38,131	0.2%
<b>17+</b>	15,024,261	98.9%	15,389,400	98.8%	15,765,394	99.0%
<b>UNSPEC.</b>	129,496	0.9%	151,308	1.0%	114,244	0.7%
<b>glyburide</b>	8,931,867	12.7%	8,856,863	12.0%	8,927,925	11.2%
<b>0-16</b>	5,599	0.1%	4,925	0.1%	4,337	0.0%
<b>17+</b>	8,865,505	99.3%	8,771,021	99.0%	8,864,535	99.3%
<b>UNSPEC.</b>	60,763	0.7%	80,917	0.9%	59,053	0.7%
<b>glimepiride</b>	6,459,540	9.2%	6,728,550	9.1%	7,196,239	9.1%
<b>0-16</b>	6,283	0.1%	5,890	0.1%	4,210	0.1%
<b>17+</b>	6,405,971	99.2%	6,664,005	99.0%	7,152,282	99.4%
<b>UNSPEC.</b>	47,286	0.7%	58,655	0.9%	39,747	0.6%
<b>glyburide/metformin hcl</b>	6,194,450	8.8%	5,891,629	8.0%	5,568,894	7.0%
<b>0-16</b>	4,609	0.1%	3,316	0.1%	2,167	0.0%
<b>17+</b>	6,158,038	99.4%	5,858,300	99.4%	5,548,554	99.6%
<b>UNSPEC.</b>	31,803	0.5%	30,013	0.5%	18,173	0.3%
<b>glyburide micronized</b>	1,169,287	1.7%	1,000,308	1.4%	893,855	1.1%
<b>0-16</b>	518	0.0%	386	0.0%	317	0.0%
<b>17+</b>	1,159,672	99.2%	991,956	99.2%	889,018	99.5%
<b>UNSPEC.</b>	9,097	0.8%	7,966	0.8%	4,520	0.5%
<b>glipizide/metformin hcl</b>	463,332	0.7%	448,158	0.6%	413,606	0.5%
<b>0-16</b>	417	0.1%	327	0.1%	245	0.1%
<b>17+</b>	460,156	99.3%	445,547	99.4%	411,970	99.6%
<b>UNSPEC.</b>	2,759	0.6%	2,284	0.5%	1,391	0.3%

Verispan, LLC, Vector One® National (VONA) Data extracted 9-21-06; File: A060093 9-21-06 Amaryl TRxAge Unrounded.qry

\*Subtotals may not sum exactly, due to rounding error.

In contrast to dispensed prescription data, the projected number of all patients receiving a prescription for Amaryl® (glimepiride) in the retail pharmacy setting decreased from approximately 1.3 million patients during the pre-exclusivity period (July 2004 – June 2005) to approximately 918,000 patients in the post exclusivity period (July 2005 – June 2006) (Table 3). This represented a decrease of approximately 28% from the pre- to post-exclusivity periods.

The number of pediatric patients receiving a prescription for Amaryl® decreased by 52% from approximately 1,901 patients during the pre-exclusivity period (July 2004 – June 2005) to approximately 904 patients during the post-exclusivity period (July 2005 – June 2006). In adults age 17 years and older,

the number of patients receiving a prescription for Amaryl<sup>®</sup> decreased by almost 28% from over 1.2 million during the pre-exclusivity period to approximately 903,519 patients during the post-exclusivity period. Similar to dispensed prescription data, pediatric patients represented less than 1% of the total number of patients receiving a prescription for Amaryl<sup>®</sup> in the outpatient retail pharmacy setting.

**Table 3. Total Number of Patients Receiving Prescriptions Through Retail Pharmacies for Amaryl<sup>®</sup> by Patient Age, During July 1, 2003 through June 30, 2006\* (mail order pharmacies not included)**

	July 2003 - June 2004		July 2004 - June 2005		July 2005 - June 2006	
	Projected Patient Count	Total Patient Share	Projected Patient Count	Total Patient Share	Projected Patient Count	Total Patient Share
<b>Amaryl<sup>®</sup> (glimepride)</b>	<b>1,232,408</b>	<b>100.0%</b>	<b>1,266,627</b>	<b>100.0%</b>	<b>917,659</b>	<b>100.0%</b>
Age 0 - 16	2,143	0.2%	1,901	0.2%	904	0.1%
Age 17+	1,218,624	98.9%	1,250,609	98.7%	903,519	98.5%
Unknown Age	39,878	3.2%	42,885	3.4%	24,908	2.7%

Verispan, LLC, Total Patient Tracker, Extracted 8-28-06; File: TPT A060093 8-28-06 Amaryl BPCA 0-16, 17+.xls

\*Subtotals may not sum exactly, due to rounding error., Due to aging of patients during the study period ("the cohort effect"), patients may be counted more than once in the individual age categories. For this reason, summing across age bands is not advisable and will result in overestimates of patient counts.

### **III. Prescriber Specialty**

General Practitioners (including general practice, family medicine, Doctors of osteopathy) and Internal Medicine specialties were the two most frequent prescribers of Amaryl<sup>®</sup> (glimepiride) in each of the three 1-year periods of observation, accounting for nearly 40% and 35-36% of retail prescriptions, respectively (Table 4). Endocrinologists accounted for no more than 7% of dispensed prescriptions in the entire 36-month period. Pediatricians were the ninth most frequent prescribers during each year with approximately 0.9% of prescriptions during all three time periods.

**Table 4: Total Number of Retail Prescriptions Dispensed (in thousands) for Amaryl<sup>®</sup> by Top 10 Prescriber Specialties, During July 1, 2003 through June 30, 2006 (mail order pharmacies not included)**

	July 2003 - June 2004		July 2004 - June 2005		July 2005 - June 2006	
	TRxs (000)	Share %	TRxs (000)	Share %	TRxs (000)	Share %
<b>Amaryl<sup>®</sup> (glimepiride)</b>	<b>6,460</b>	<b>100.0%</b>	<b>6,729</b>	<b>100.0%</b>	<b>7,196</b>	<b>100.0%</b>
GP/FM/DO*	2,523	39.1%	2,576	38.3%	2,831	39.3%
Internal Medicine	2,229	34.5%	2,332	34.7%	2,565	35.6%
Endocrinology	362	5.6%	416	6.2%	481	6.7%
Unspecified	567	8.8%	597	8.9%	423	5.9%
Nurse Practitioner	90	1.4%	106	1.6%	130	1.8%
Cardiovascular Diseases	112	1.7%	113	1.7%	126	1.7%
Physician Assistant	60	0.9%	69	1.0%	83	1.2%
Hospital	67	1.0%	71	1.0%	74	1.0%
<b>Pediatrics</b>	<b>56</b>	<b>0.9%</b>	<b>60</b>	<b>0.9%</b>	<b>67</b>	<b>0.9%</b>
Nephrology	46	0.7%	48	0.7%	53	0.7%

All Others	346	5.4%	342	5.1%	363	5.0%
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\* GP/FM/DO - General Practice, Family Medicine, Doctors of Osteopathy  
 Verispan, LLC. Vector One® National (VONA) Data extracted 8-23-2006  
 File: A060093 8-23-06 Amaryl BPCA MD.qry

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#### **IV. Indication for Use**

The most common indication for use of Amaryl® (glimepiride) during office-based visits of adult patients was “Diabetes Mellitus Uncomplicated” (ICD-9 250.0), which accounted for approximately 95% of adult Amaryl® diagnosis mentions in both the pre- and post-exclusivity periods.<sup>4</sup> No visit for pediatric patients during which Amaryl® was mentioned was recorded during the entire three-year time period.

#### **DISCUSSION**

Based on the databases employed for this analysis, total dispensed retail prescriptions for the selected seven anti-hyperglycemic agents (glimeperide, glipizide, glyburide, glyburide micronized, metformin, glipizide/metformin and glyburide/metformin) increased by approximately 13% from the pre-exclusivity period (July 2003 – June 2004) to the post-exclusivity period (July 2005 – June 2006). However, the use of these anti-hyperglycemic agents including Amaryl® in the pediatric population was low, accounting for only 1% of the total patients using those agents. This finding is supported by the relatively low incidence rate of Type 2 diabetes in this population, though this rate has been increasing in the last two decades.<sup>5, 6</sup>

Findings from this consult should be interpreted in the context of the known limitations of the databases used. We estimated that Amaryl® was distributed primarily in outpatient settings based on the IMS Health, IMS National Sales Perspectives™. These data do not provide a direct estimate of use, but do provide a national estimate of units sold from the manufacturer into the various channels of distribution, including mail order, which is the second most common retail distribution channel, accounting for up to 21% of the wholesale sales.<sup>7</sup> The amount of product purchased by these retail and non-retail channels of distribution may be a possible surrogate for use, if we assume the facilities purchase drugs in quantities reflective of actual patient use.

While we conducted a comprehensive analysis of the use of Amaryl® in the outpatient settings, where the majority of use occurred, a significant proportion of the wholesale sales of Amaryl® is to mail order pharmacies; a distribution channel not currently captured by Verispan’s retail prescription audits.

Verispan’s Physician Drug & Diagnosis Audit (PDDA) data provide estimates of patient demographics and indications for use of medicinal products in the U.S. Due to the sampling and data collection methodologies, the small sample size can make these data unstable, particularly if use is not common in the pediatric population. Verispan recommends caution interpreting the projected annual uses or mentions below 100,000 as the sample size is very small with correspondingly large confidence intervals.

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<sup>4</sup> Verispan, LLC. Physician Drug and Diagnosis Audit, Extracted 9-21-06; File: PDDA A060093 Amaryl BPCA AgDx.xls

<sup>5</sup> Hannon TS, Rao G, Arslanian SA. Childhood obesity and type 2 diabetes mellitus. *Pediatrics*. 2005 Aug;116(2):473-80. PMID: 16061606

<sup>6</sup> Kaufman FR. Type 2 diabetes in children and youth. *Endocrinol Metab Clin North Am*. 2005 Sep;34(3):659-76, ix-x. PMID: 16085165

<sup>7</sup> IMS Health, IMS National Sales Perspectives™, Data extracted 8-2006, File: 0608amar.dvr

## CONCLUSION

In summary, total dispensed prescriptions for the selected seven anti-hyperglycemic agents (glimeperide, glipizide, glyburide, glyburide micronized, metformin, glipizide/metformin and glyburide/metformin) increased by nearly 8% from the pre- to the post-exclusivity time periods. The overall number of prescriptions dispensed for Amaryl<sup>®</sup> (glimepiride) increased for adults, but decreased for the pediatric population. In contrast, the number of patients receiving a prescription for Amaryl<sup>®</sup> decreased in both adult and pediatric populations during this time period. Pediatric patients accounted for less than 1% of the total dispensed prescriptions for Amaryl<sup>®</sup> as well as patients during the entire study period.

General Practitioners and Internal Medicine specialties were the most frequent prescribers of Amaryl<sup>®</sup> and together accounted for nearly 75% of all dispensed prescriptions during the entire study period. The indication for use most frequently linked to Amaryl<sup>®</sup> in adults was “Diabetes Mellitus Uncomplicated” (ICD-9 250.0). No visit for pediatric patients during which Amaryl<sup>®</sup> was mentioned was recorded during the study period.

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## **APPENDIX**

### **IMS HEALTH**

#### *IMS National Sales Perspectives™*

IMS Health, IMS National Sales Perspectives™ measures the volume of drug products (both prescription and over-the-counter) and selected diagnostic products moving from manufacturers into various outlets within the retail and non-retail markets. Outlets within the retail market include the following pharmacy settings: chain drug stores, independent drug stores, mass merchandisers, food stores, and mail service. Outlets within the non-retail market include clinics, non-federal hospitals, federal facilities, HMOs, long-term care facilities, home health care, and other miscellaneous settings. IMS Health, IMS National Sales Perspectives™ measures the volume of drug products moving from manufacturer into retail and non-retail settings in terms of sales dollars, vials, and market share. These data are based on national projections.

Data for this analysis include prescriptions dispensed for Amaryl® from years 2003 through 2005, inclusive.

### **VERISPAN, LLC**

#### Vector One®: National (VONA)

Verispan's VONA is a nationally projected database which measures the retail dispensing of prescriptions or the frequency with which drugs move out of retail pharmacies into the hands of consumers via formal prescriptions. Information on the physician specialty, the patient's age and gender, and estimates for the numbers of patients that are continuing or new to therapy are available.

The Vector One® database integrates prescription activity from a variety of sources including national retail chains, mass merchandisers, pharmacy benefits managers and their data systems, and provider groups. Vector One® receives over 2 billion prescription claims, representing over 160 million unique patients.

The number of dispensed prescriptions is obtained from a sample of virtually all retail pharmacies throughout the U.S and represents approximately half of the retail prescriptions dispensed nationwide. Verispan receives all prescriptions from approximately one-third of the stores and a significant sample of prescriptions from the remaining stores. Mail order prescriptions are not included in the sample at this time.

Data for this analysis include prescriptions dispensed for Amaryl® (glimepiride) as well as glipizide, glyburide, glyburide micronized, metformin, glipizide/metformin and glyburide/metformin from July 1, 2003 through June 30, 2006, inclusive.

### **VERISPAN, LLC**

#### Vector One®: Total Patient Tracker (TPT)

Verispan's Total Patient Tracker is a national-level projected audit designed to estimate the total number of unique patients across all drugs and therapeutic classes.

TPT derives its data from the Vector One® database which integrates prescription activity from a variety of sources including national retail chains, mass merchandisers, pharmacy benefits

managers and their data systems, physician offices and hospitals. Vector One® receives over 2 billion prescription claims per year, which represents over 160 million patients tracked across time.

Data for this analysis include patients who were dispensed a prescription for Amaryl® from July 1, 2003 through June 30, 2006, inclusive.

***VERISPAN, LLC***

**Physician Drug & Diagnosis Audit (PDDA)**

Verispan's Physician Drug & Diagnosis Audit (PDDA) is a monthly survey that monitors disease states and the physician intended prescribing habits on a national-level. The survey is designed to provide descriptive information on the patterns and treatment of diseases encountered in office-based physician practices in the U.S. The audit is composed of approximately 3,100 office-based physicians representing 29 specialties across the United States that report on all patient activity during one typical workday per month. These data may include profiles and trends of diagnoses, patients, drug products mentioned during the office visit and treatment patterns. The data are then projected nationally by physician specialty and region to reflect national prescribing patterns.

The term drug uses refers to mentions of a drug in association with a diagnosis during an office-based patient visit. This term may be duplicated by the number of diagnosis for which the drug is mentioned. It is important to note that a drug use does not necessarily result in prescription being generated. Rather, the term indicates that a given drug was mentioned during an office visit.

Data for this analysis include physician mentions for Amaryl® from July 1, 2003 through June 30, 2006, inclusive.

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/s/

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9/28/2006 05:14:27 PM  
DRUG SAFETY OFFICE REVIEWER

Solomon Iyasu  
9/29/2006 09:32:40 AM  
MEDICAL OFFICER