

DEC 4 2007

2



TEVA PHARMACEUTICALS USA

Confidential and Proprietary

November 28, 2007

Kimberly Howell  
Centers for Medicare and Medicaid  
Department of Health and Human Services  
Attn: CMS-2238-FC  
Mail Stop: C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-8012

Dear Ms Howell:

The intent of this letter is to document the policies and practices adopted by Teva Pharmaceuticals USA, Inc. (Teva), as a result of the Deficit Reduction Act (DRA) final rule. Teva processes Average Manufacturer Prices (AMPs) and Best Prices (BPs) for the following labeler codes and corresponding firm names:

1. 00093 Teva Pharmaceuticals USA, Inc.
2. 00172 Ivax Pharmaceuticals, Inc.
3. 00182 Goldline Laboratories, Inc.
4. 00332 Biocraft Laboratories, Inc.
5. 00575 Ivax Research, LLC (formerly Ivax Research, Inc.)
6. 00703 Teva Parenteral Medicines, Inc. (formerly Sicor Pharmaceuticals, Inc.)
7. 38245 Copley Pharmaceutical, Inc.
8. 55953 Novopharm USA, Inc.
9. 57844 Gate Pharmaceuticals, a division of Teva Pharmaceuticals USA, Inc.
10. 59310 Teva Specialty Pharmaceuticals, LLC (formerly Ivax Labs, Inc.)
11. 68546 Teva Neuroscience, Inc.

Teva processes have been amended to comply with the new regulations and the following guidelines specify Teva's interpretation of the regulations:

1. Administration Fees

Administration Fees for retail entities that are not considered bona fide service fees under the final rule will be included in the Average Manufacturer Price (AMP) calculation as a deduction from the retail sales. Teva generally does not treat Administration Fees that are calculated as a percentage of sales as bona fide administration fees as defined in the final rule. Other Administration Fees will be reviewed individually to determine if they are deemed bona fide or not.

2. AMP Transaction Date

For the calculation of AMP, Teva uses the transactions' "paid date" rather than "earned date" to document the period in which the lagged price concession occurred. Teva considers the



TEVA PHARMACEUTICALS USA

Confidential and Proprietary

following transaction types to be lagged price concessions subject to smoothing over a 12-month period:

- a. Non-bona fide Administration Fees per the DRA final rule definition
- b. Chargebacks paid to wholesalers and distributors
- c. Rebates
- d. Billing/Pricing Adjustment Transactions
- e. Exempted Government and 340B Indirect Sales (e.g., sales to 340B, VA or OGA customers)
- f. Exempted Non-retail Indirect Sales (e.g., sales to hospitals and long term care facilities)

Teva will smooth the above items as per the provisions of the DRA final rule. The smoothing methodology is elaborated in section seven (7).

### 3. Best Price

#### a. Transaction Date

To calculate the Best Price for a given quarter, Teva will use the transactions' "paid date" rather than the lagged "earned date" for any eligible price concessions detailed in section two (2).

For each NDC-9, sales and rebates are aggregated and then calculated on a sales and rebate per unit level respectively. The Best Price is then calculated as the lowest net sale amount resulting from the sales amount per unit, less the calculated prompt pay discount and rebate amount per unit.

#### b. Return Transactions

Teva will not include return transactions in its Best Price calculations because it is not a price but a reversal of a prior shipment.

### 4. Class of Trade Definitions

Following the DRA final rule dissemination, Teva revised its classes of trade as follows:

#### a. Health Maintenance Organizations (HMOs)

Teva's HMO class of trade includes the following organization types:

- i. *Closed-panel (Staff-model) HMOs* - These organizations only allow patients to receive services through a limited number of providers in which the physicians are employees of the HMO. The providers see members in the HMO's own facilities. In addition, the entities own and operate licensed pharmacies that serve only members of that HMO.
- ii. *Independent Practice Association (IPA) HMOs* - The organizations are composed of a group of independently practicing physicians who maintain their own offices and band together to contract their services with HMOs, PPOs (preferred provider organizations), and insurance companies. An IPA may contract with and provide services to both HMO and non-HMO plan participants.



- iii. *Integrated Health Systems* - These systems may include multiple hospitals and specialty care centers, but the Integrated Health System handles all purchasing for the system. Examples include Tenet and Kaiser.

Organizations that Teva classifies as HMOs take possession of drugs. Both sales and rebates to HMOs will be excluded from AMP.

b. Pharmacy Benefits Managers (PBMs)

Teva defines PBMs as "Service Provider" organizations which assist health insurers and employers with the management of the medical and/or prescription drug benefit offered to health plan members. Services offered by PBMs include, but are not limited to, formulary management and control, drug utilization review, claims adjudication, negotiation and contracting with pharmaceutical companies for rebates on prescription drugs, and disease management programs.

PBMs do not share with Teva the nature of the rebate agreements between the PBM and its members; therefore, Teva is unable to distinguish between PBMs that keep all the rebates from those who share only a portion of the rebates with their members. Teva currently does not receive sufficient information from many of our PBMs to identify the mail-order portion of the PBM business and will therefore survey the PBM customers to obtain an estimated percentage of mail-order business to include in the AMP calculation and request utilization breakouts for mail order portions of rebates in the future.

Mail-order sales and identified rebates for PBMs will be included in AMP. Non-mail order sales will be included in AMP, but related rebates will be excluded from the AMP calculation.

c. Managed Care Organizations (MCOs)

Teva defines MCOs as health insurers, medical groups and hospitals that are accountable for health care where the goal is to deliver quality, cost effective health care through monitoring and recommending utilization of services to a group of people enrolled to receive health care services. Teva currently does not receive sufficient information to identify the mail-order portion of the MCO business. Therefore, Teva will survey MCO customers to determine if reliable information can be collected to determine the breakdown of mail-order vs non mail-order rebate payments.

Teva will include sales to MCOs in AMP, but related rebates will be excluded from the AMP calculation.

5. Hospital Inpatient vs. Outpatient Facilities

As per the provisions of the DRA final rule, Teva's policy is to treat all hospitals as "inpatient" facilities unless otherwise identified as an "outpatient" facility per the DEA/HIN tape. Outpatient hospitals will be classified as clinics and treated as retail customers.

6. Prompt Pay Discounts

As per the DRA final rule requirements, Teva will report prompt pay discount amounts to CMS. However, Teva accounting systems do not capture this information at either a 9 or 11 digit NDC level. Therefore, it is Teva's intent to report all prompt pay discount amounts for the required reporting period as an aggregated amount across all Teva drugs on a quarterly basis.

7. Smoothing Methodology

Teva will smooth lagged price concessions as per the provisions of the DRA final rule. The smoothing methodology of each lagged price concessions is depicted below.

a. *Non-bona fide Administration Fees, Billing/Pricing Adjustments, Chargebacks and Rebates*

These will be smoothed using a rolling twelve (12) months of Adjusted Direct Sales. For any time period, Adjusted Direct Sales are defined as the period's Gross Direct Sales less the period's Government Direct Sales, Non-Retail Direct Sales, Smoothed Government Indirect Sales and Smoothed Non-retail Indirect Sales.

For example, Monthly Non-Bona Fide Administration Fees will be calculated as follows:

*Monthly Non-Bona Fide Administration Fees =*

$$\left( \frac{\text{Rolling 12 Months Administration Fees}}{\text{Rolling 12 Months Adjusted Net Sales}} \right) \times (\text{Current Month Adjusted Net Sales})$$

b. *Exempted Government Indirect Sales and Exempted Non-retail Indirect Sales*

These will be smoothed using a rolling twelve (12) months of Net Direct Sales units. For any time period, Net Direct Sales are defined as the period's Gross Direct Sales less the period's Government Direct Sales and Non-Retail Direct Sales.

For example, monthly Government Indirect Sales will be calculated as follows:

*Monthly Government Indirect Sales Units =*

$$\left( \frac{\text{Rolling 12 Months Government Indirect Units}}{\text{Rolling 12 Months Net Direct Sales Units}} \right) \times (\text{Current Month Net Direct Sales Units})$$

*Monthly Government Indirect Sales Dollars =*

$$(\text{Monthly Government Indirect Sales Units}) \times (\text{WAC Proxy}),$$

where WAC proxy is defined as the average units price to wholesalers for the period in question

8. Third Party Sales and Credit Data

Teva does not control indirect sales data submitted by wholesalers for chargebacks. If such data is found to be incorrect, then Teva relies on the wholesaler to correct and resubmit the data. In addition, Teva does not receive end-customer sales data via chargebacks from some wholesalers or any distributors. Further, Teva relies on the submission of PBMs to advise on mail-order utilization allocations for rebates.



TEVA PHARMACEUTICALS USA

**Confidential and Proprietary**

Request for Response

We thank you in advance for your attention to this letter. We will go forward with these guidelines starting at the October 2007 reporting period. We request that you direct the formal response to the address below.

Teva North America  
1090 Horsham Road  
PO Box 1090  
North Wales, PA 19454-1090  
Attn: John Wodarczyk

If you would like to discuss any aspect of this letter, I can be reached via telephone at 215.591.3021 or email at [john.wodarczyk@TevaUSA.com](mailto:john.wodarczyk@TevaUSA.com).

Sincerely,

A handwritten signature in black ink, appearing to read "John Wodarczyk", written over the word "Sincerely,".

John Wodarczyk

Director, Customer Operations