

David A. Velez  
Executive Director,  
Federal Healthcare Affairs  
USHH Managed Care

Merck & Co., Inc.  
P.O. Box 4, WP39-403  
West Point, PA 19486-0004  
tel. (215) 652-1656  
E-mail: [velezdav@merck.com](mailto:velezdav@merck.com)



***Sent via Federal Express***

Wyman Ford, R. Ph.  
Contracting Director  
Indian Health Services  
Regional Supply Service  
1005 N. Country Club Rd.  
Ada, OK 74820

CAPT Robert Pittman  
IHS Principal Pharmacy Consultant  
Director, Risk Management  
801 Thompson Ave.  
Suite 300  
Rockville, MD 20852

October 27, 2004

Dear Sirs,

On September 30, 2004, Merck announced that it was to immediately and voluntarily withdraw VIOXX® (rofecoxib) from the market. Merck announced specific actions that it was taking to inform patients of the product withdrawal. We have received some requests to compensate for the expenses incurred in communicating the voluntary product withdrawal to patients.

Although the voluntary withdrawal was executed at the pharmacy level, Merck recognizes the role your organization can help play in providing information to patients about the product withdrawal. For this reason, Merck is pleased to offer reimbursement for your expenses in sending written communications to patients in accordance with the following terms and conditions.

**Terms and conditions for reimbursement of communications resulting from and concerning the voluntary withdrawal of VIOXX®:**

Merck will reimburse the IHS for written communications mailed to patients resulting from and specifically concerning the voluntary withdrawal of VIOXX, made between September 30, 2004 and November 15, 2004 as provided in this letter. There will be no reimbursement for phone calls, emails, contacts from a website, or any other communications other than written communications mailed to patients on IHS's letterhead. There will be no reimbursement for multiple letters to the same patient, regardless of the number of prescriptions filled and refilled during the relevant period. IHS acknowledges that it has received information from Merck regarding the voluntary withdrawal of VIOXX, including instructions for patients to receive refunds for unused product. Additional information or clarification is available from Merck upon request. IHS understands and agrees that the content of its communication to patients is solely the responsibility of the IHS; however, we do request that any

communication made after the date of this letter be consistent with Merck's instructions for patients to receive refunds and include the 800-number we have made available for that purpose (**1-800-805-9542**). Merck will not draft or review any communications.

In order to qualify for reimbursement, IHS must agree to use reasonable efforts to identify the appropriate patients to receive the communication and send the communication to all patients so identified. We will only reimburse you for communications to patients who have been dispensed a new or refill prescription for VIOXX after October 1, 2003.

Merck agrees to pay IHS the sum of \$0.40 per written, mailed eligible communication supported by IHS's data. The parties stipulate and agree that this amount represents the fair market value of the agreed upon costs.

IHS agrees that it will not provide any patient identifiable information to Merck, including names, addresses, insurance numbers, co-pays, physician names, clinic, telephone numbers or any other Protected Health Information. Failure to comply with this obligation will be viewed as a breach of agreement and will release Merck from any obligation hereunder.

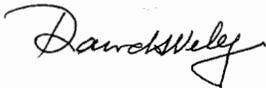
Required data to be submitted to Merck on or before December 15, 2004 shall consist of the identifying criteria used to select patients and the number of communications sent for which reimbursement is sought, specifying the date the communication was sent to patients. All such data must be submitted in writing with the appropriate signature of a duly authorized representative of IHS. The signature shall represent certification of the accuracy of the submitted data and such data shall be subject to inspection, examination and audit by a third party auditor selected and compensated by Merck. IHS must also provide a specimen copy of the patient communication that was sent. If overcharges of any nature occur, adjustments shall be made by IHS within a reasonable amount of time, not to exceed ninety days (90) from discovery of the inaccuracy, whether discovered by Merck or DoD.

No extra payment will be given for special delivery, federal express, express mail, registered mail, or any other form of delivery. No credit or exchange will be allowed for reimbursement. Reimbursement shall be in the form of a check made payable to IHS.

IHS agrees to maintain appropriate records of all communications to patients for which it seeks reimbursement for a period of not less than five years.

Please acknowledge below your acceptance of this reimbursement offer and return a signed copy of this letter to Keith A. French, RN (at the address indicated below) along with your required data, in no event later than December 15, 2004.

Sincerely,



David A. Velez  
Executive Director  
Federal Healthcare Affairs  
USHH Managed Care, Merck & Co., Inc.

**AGREEMENT BY IHS**

I accept the foregoing reimbursement offer and agree to the terms and conditions thereof.

We have queried our database for the period below, using the identification criteria listed below. We have identified the following number of appropriate patients to receive a communication regarding the voluntary withdrawal of VIOXX, all of whom have been sent such communication in accordance with the terms of this letter on \_\_\_\_\_ [date]. A specimen copy of the communication that was sent to patients is enclosed.

Query Start Date: (MM/YYYY)

Query End Date: (MM/YYYY)

Patient identification criteria: \_\_\_\_\_

\_\_\_\_\_

Number of patients receiving letters: \_\_\_\_\_ [Line A]

Reimbursement Formula: Line A times

TOTAL REIMBURSEMENT SOUGHT: LINE A times \$0.40  
= \_\_\_\_\_

I verify that the information provided above is true, accurate and complete.

NAME: (PRINT) \_\_\_\_\_

TITLE: \_\_\_\_\_

INSTITUTION: \_\_\_\_\_

SIGNATURE: \_\_\_\_\_

DATE: \_\_\_\_\_

Return to:  
Keith A. French, RN  
Associate Director  
Pharmacy & Senior Health  
770 Sumneytown Pike WP 39-248  
West Point, PA 19486  
Fax: 215-652-5308

David A. Velez  
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1005 N. Country Club Rd.  
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CAPT Robert Pittman  
IHS Principal Pharmacy Consultant  
Director, Risk Management  
801 Thompson Ave., Suite 300  
Rockville, MD 20852

October 27, 2004

Dear Sirs:

On September 30, 2004, Merck announced that it was immediately and voluntarily withdrawing VIOXX® (rofecoxib) from the market. On October 1, we notified you that VIOXX would no longer be part of your contract(s) with Merck.

Merck announced specific actions that it was taking to inform patients of the product withdrawal. In addition, Merck announced that it will provide patients with a refund for any unused VIOXX tablets or suspension that is returned with a pharmacy receipt to the National Notification Center (NNC), an independent company contracted by Merck, for handling all returns of VIOXX. Patients are instructed to call NNC at **1-800-805-9542** for a Patient Return Kit that includes an instruction sheet with guidelines for the return, a shipping container, and a pre-paid shipping label. We recognize that Indian Health Service ("IHS") patients do not have expenses in association with their prescriptions and may have returned their unused VIOXX tablets to their IHS or authorized tribal Clinic, collectively "IHS Facilities".

In any effort to provide the Indian Health Services with the opportunity to return non-dispensed inventory as well as receive reimbursement for product that cannot be used due to the withdrawal of VIOXX, Merck is implementing the following procedure for IHS facilities:

1. Non-dispensed Inventory: (Non-dispensed inventory should be returned separately from unused/returned inventory). Individual IHS facilities will return non-dispensed VIOXX inventory to NNC, for the appropriate credit. (Attachment 1). Credit will be calculated based on the number of units returned and at the corresponding FSS or Incentive Agreement price, as appropriate, in effect on

September 30, 2004. Credit will be provided to individual IHS facilities in the form of a prime vendor credit to account(s) to be determined by Merck and IHS.

2. Unused/returned Inventory: (Non-dispensed inventory should be returned separately from unused/returned inventory). To the extent that patients return unused VIOXX to IHS facilities, individual IHS facilities will consolidate the returned unused VIOXX and return it to NNC for appropriate credit. Credit will be calculated based on the number of units returned and at the corresponding FSS or Incentive Agreement price, as appropriate, in effect on September 30, 2004. Credit will be provided to individual IHS facilities in the form of a prime vendor credit to account(s) to be determined by Merck and IHS.

Consolidated returns should be accompanied by a complete and accurate itemized list of the following information to NNC no later than December 31, 2004:

- (a) number of returned tablets for each patient,
- (b) if oral suspension, volume returned for each patient,
- (c) tablet strength (12.5mg, 25mg or 50mg),
- (d) original pharmacy container with returned product,
- (e) dispensing date of prescription being refunded.

IHS Mailings to Patients:

It is the subject of a separate letter.

Other:

IHS agrees that it will not provide any patient identifiable information or other Protected Health Information to Merck. Merck requests IHS to maintain patient-specific records of transactions related to this matter for a period of at least five (5) years.

Your National Account Executive will be contacting you in the near future to answer any questions you may have regarding this letter.

Attachments:

Attachment 1



pharmacist  
notification FINAL ...

Vioxx Label



VIOXXLabel.pdf  
(122 KB)

Sincerely,

David A. Velez  
Executive Director,  
Federal Healthcare Affairs  
USHH Managed Care  
Merck & Co., Inc.



## **Merck Announces Voluntary Worldwide Withdrawal of VIOXX**

Dear Pharmacist:

Merck & Co., Inc. today announced a voluntary worldwide withdrawal of VIOXX (rofecoxib), its arthritis and acute pain medication. The Company's decision, which is effective immediately, is based on new, three year data from a prospective, randomized, placebo-controlled clinical trial, the APPROVe (Adenomatous Polyp Prevention on VIOXX) trial.

The trial, which is being stopped, was designed to evaluate the efficacy of VIOXX 25mg in preventing recurrence of colorectal polyps in patients with a history of colorectal adenomas. In this study, there was an increased relative risk for confirmed cardiovascular (CV) events, such as heart attack and stroke, beginning after 18 months of treatment in the patients taking VIOXX compared to those taking placebo. The results for the first 18 months of the APPROVe study did not show any increased risk of confirmed CV events on VIOXX, and in this respect are similar to the results of two placebo-controlled studies described in the current US labeling for VIOXX.

We are taking this action because we believe it best serves the interests of patients. Although we believe it would have been possible to continue to market VIOXX with labeling that would incorporate these new data, given the availability of alternative therapies, and the questions raised by the data, we concluded that a voluntary withdrawal is the responsible course of action.

APPROVe was a multi-center, randomized, placebo-controlled, double blind study to determine the effect of 156 weeks (3 years) of treatment with VIOXX on the recurrence of neoplastic polyps of the large bowel in patients with a history of colorectal adenoma. The trial enrolled 2600 patients, and compared VIOXX 25 mg to placebo. The trial began enrollment in 2000.

Results of the VIGOR (VIOXX GI Outcomes Research) study, released in March 2000, demonstrated that the risk of gastrointestinal (GI) toxicity with VIOXX was less than with naproxen, but indicated an increased risk of cardiovascular events versus naproxen. However, in other studies including our Phase III studies that were the basis of regulatory approval of the product, there was not an increased risk of CV events on VIOXX compared with placebo or VIOXX compared with other non-naproxen NSAIDs. Merck

VIOXX is a registered trademark of Merck & Co., Inc.

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began long-term randomized clinical trials to provide an even more comprehensive picture of the cardiovascular safety profile of VIOXX.

Merck has always believed that prospective, randomized, controlled clinical trials are the best way to evaluate the safety of medicines. APPROVe is precisely this type of study-- and it has provided us with new data on the cardiovascular profile of VIOXX. While the cause of these results is uncertain at this time, they suggest an increased risk of confirmed CV events beginning after eighteen months of continuous therapy. While Merck recognizes that VIOXX benefited many patients, we believe this action is appropriate.

Merck has informed the FDA of its decision. Pharmacists should stop dispensing VIOXX immediately. Patients who are currently taking VIOXX should contact their health care providers to discuss discontinuing use of VIOXX and possible alternative treatments.

National Notification Center (NNC), an independent company contracted by Merck, will contact you within 3 to 5 business days with instructions on how to return undispensed product and receive appropriate credit.

If a patient asks the pharmacist about returning unused VIOXX, please advise the patient that Merck will reimburse them for the cost of unused product. Instructions for patient reimbursement are attached and are posted at [www.vioxx.com](http://www.vioxx.com) and can be obtained by calling NNC directly at 1-800-805-9542.

Patients and health care professionals may obtain additional information from [www.merck.com](http://www.merck.com) and [www.vioxx.com](http://www.vioxx.com), or may call 1-888-36-VIOXX (1-888-368-4699).

The Prescribing Information for VIOXX accompanies this letter.

Sincerely,



William F. Keane, MD  
Vice President  
US Medical and Scientific Affairs

## **Instructions for patients on how to receive refund for unused VIOXX®**

Merck will reimburse patients for unused VIOXX® (rofecoxib).

Merck is offering patients a full refund for the amount they paid out-of-pocket for VIOXX® prescriptions that remained unused as of September 30, 2004.

Patients seeking a refund for unused VIOXX® should contact the National Notification Center (NNC) at 1-800-805-9542. Patients who call that number will receive a patient return kit directly from NNC which may be returned via UPS (United Parcel Service). The return kit includes a shipping container and a prepaid UPS shipping label, with complete instructions. Completed return kits can be placed into a UPS drop or delivered to a UPS drop-off location, or the patient can arrange for pick-up by calling UPS at 1-800-PICK-UPS.

Refunds may take four to six weeks.