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To: Distribution Below

From: G. Moss

Subject: International Monthly Report – April 2009

Date: [DATE \@ "MMMM d, yyyy"]

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E. Davis
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E. Falla
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M. Kelly
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N. Litzsinger

D. Lugge
J. MacDonald
T. Missey
A. Montano
T. Nieters
T. Palmer
B. Potter
J. Rausch
D. Von Rohr
S. Wu

PAP/APAP

Canada

- McNeil volume was on forecast at 50 MT powder and 32 MT Compap L. Current YTD volumes compared to last YTD are level for powder and 20 MT over for Compap L.
- McNeil have begun paying the full invoice price of USD 5.88 per kilogram for powder. However, we still have a total of 9 invoices, issued over the past few months that have been underpaid for a total of USD 26,989. This occurred during the period that Fort Washington advised them not to accept the new pricing.
- Accucaps cancelled a 16 MT order scheduled to ship in April, due to reduced demand from P&G. Their YTD quantity is still 16 MT over last YTD.
- Pharmetics is bidding on a project for a European client that would require about 110 MT of Compap PVP3. A quote for code 3930 has been submitted to Pharmetics.
- Labopharm are working on an Oxycodone/APAP product, and have requested an LOA to our Canadian Compap DMF for clinical trial batches. This is a controlled-release formulation, and could impact Ratiopharm's dominant market position in Canada for the Oxy/APAP combination. Unfortunately, we were not the successful bidder for the Oxycodone portion.
- Quoted on 24 MT of Compap Coarse L for Vita Health. This is for a special project, and only represents about 15% of their annual volume.
- Apotex have requested an audit of the Raleigh APAP plant in support of Apotex Netherlands. Apotex Canada does not purchase APAP from us.
- The Pharmetics site in Fort Erie, ON, a former Patheon site, will be starting to produce an APAP product for GSK using code 0048. Timing for this is fall of 2009, but volumes are not known as yet.
- McNeil Canada has requested a sample of APAP special granular, for a new development project. They have been informed that it will be mid-June before we can supply the sample.

Japan

- PAP local sales this month were Yen33,575k(\$338k) and the volume was 43.5 MT. The volume by customer was 24.5 MT to Yamamoto, 12 MT to Iwaki, 4 MT to Tateyama and 3 MT to Nippon Junryo.
- Yamamoto placed a new order for 24.5 MT (40 FCL) of PAP, 0147 for May delivery through Okahata Sangyo, a distributor. After this order, new orders are expected for 24.5 MT monthly for the remaining FY09.
- Iwaki placed a new order for 4 MT of PAP, 0147 and another 4 MT is expected for May delivery. Total sales volume will be 8 MT at a normal consumption level.
- Nippon Junryo placed a new order for 3 MT of PAP, 0147 for May delivery, in addition to 3 MT this month. It is a little favorable from our previous sales estimate.
- APAP local sales this month were Yen18,323k (\$185k) and the volume was 15.6 MT. The volume by customer was 8 MT of code 7845 to Mitsuba, 4 MT of code 6375 to Daiichi Sankyo, 2.5 MT of code 6375 to Takeda, 1 MT of code 6375 to Fuji

and 0.1 MT of code 1617 to Lion.

- Daiichi-Sankyo placed the first order for 4 MT of APAP, code 6375 at Yen1,200(\$12.09) per kilogram. It was delivered from our inventory this month. They are our customer for Noscapine, Fentanyl Citrate and Magnesium Stearate as well.
- Takeda placed a new order for 2.3 MT of APAP, code 6375 at Yen1,200(\$12.09) per kilogram for July delivery.
- Yamamoto placed a new order for 3 MT of APAP, code 6375 at Yen1,200(\$12.09) per kilogram for May delivery. They will repack and sell it to their OTC customer at their label. They are also our PAP user.
- Showa Yakuhin submitted ANDA for 500 milligram caplets using COMPAP L last year. They responded to questions and requests on the ANDA from the authorities this month. The approval is expected in January 2010.
- Janssen Japan asked to issue LOA for Japanese DMF of APAP (218MF10905). They plan to submit NDA for ULTRACET in September. The dosage will be imported from their Italian affiliate (Janssen Cilag).

Latin America

- Calier Venezuela finally received the allocation of funds from the government entity (CADIVI) to send their order for 13.5 MT of APAP to ship the end of May. Still have some past due invoices that the government has not released the monies.
- Schering Ecuador finally sent an order for 5 MT of 0048 and needed shipment as soon as possible (they simply cannot plan ahead regardless of how much we follow up with their people!).
- Presented the option of super sack packaging for their Compap® L to Schering Mexico and they will evaluate to see if they want to pursue further.
- During our past visit with Bayer Argentina, they agreed to send us the specifications for the Rhodia Rhodapap 90 they had been using so we can match it to one of our direct compression products and help them with the documentation to apply for the change in supplier. Still not received.
- Selder Mexico sent an order for 18 MT of APAP 6088 to ship last day of June.
- Import stats from Brazil for January-March 2009 show pricing from China for 100% APAP at US\$4.03 kilogram FOB, and the price for direct compression at US\$5.44 kilogram FOB.
- Import stats from Colombia for January-March 2009 show pricing from China for 100% APAP ranging from US\$3.47-US\$4.87 kilogram FOB, and for direct compression from US\$4.30-US\$6.31 kilogram FOB.

Asia/Australia

- Sales for the month amounted to \$956k which is considered respectable considering that the Chinese are back in full force. Shipments were widespread among several countries but notably in Australia, Korea and Thailand. As regards to competition, it was reported that the three (3) largest Chinese producers are: Wenzhou (Kangle Conler), Anqiu Luan and Anhui Bayi. Current pricing from the

Chinese ranges between \$3.40 - \$4.50 per kilogram and there are indications that it might continue to go up.

- My source at Unilab Philippines provided me with information regarding the company's purchase prices of Chinese APAP powder. Here are the prices:

Weistar Industry (Anqiu Luan)	-	\$ 3.45 per kg
Zhejiang Kangle	-	\$ 3.50 per kg

- Since the start of 2009, Unilab has purchased 70 and 80 MTs from Weistar and Zhejiang respectively. Currently, material from Weistar is on hold due to quality issues.
- Fortune Pharmacal deferred the placement of a new order for one (1) FCL of APAP powder as demand has somewhat slowed down as summer is approaching. They, however, reported that sales of the chewable tablet are increasing particularly in Hong Kong as they have successfully taken a chunk of GSK's share.
- Janssen Korea entered two new orders of one (1) FCL each of APAP powder with a combined value of \$240,000. Although sales of Tylenol ER are steadily increasing, the demand for Ultracet (APAP + Tramadol) is carrying the bulk of the increase that a few Korean pharmaceutical companies are in the process of introducing their own formulation using the same active ingredients. Shipments are scheduled for May and June 2009.
- Hwail Korea placed a new order of one (1) FCL of APAP powder valued at \$60,720. They recently lost some business to the Chinese early this year but managed to secure new businesses from small scale pharmaceutical companies mostly catering to the generic market.
- Won Poong placed four (4) new orders of APAP powder with a combined value of \$242,880. They supply material to Hanjin Pharm, makers of Gevorin, the second largest APAP product in Korea, after Tylenol.
- SAM-A placed a new order for 500 kilograms of Fine Powder valued at \$4,500. Product is going to be used for a new liquid suspension product catering to the pediatric market.
- Kemfar Taiwan placed a new order for 200 kilograms of APAP Microcaps code 4037 valued at \$6,000. Material is to be supplied to Yung Shin Pharm as there is renewed demand for chewable tablets.
- We completed the shipment of two (2) FCL of APAP fine powder to South City with a combined value of \$104,800. Material is to be supplied mostly to Thai Nakorn for their liquid suspension product.
- Boehringer Ingelheim Indonesia has a requirement of 1,600 kilograms of APAP powder for immediate shipment, with a value of \$14,400. P.T. Waris will soon be placing a new order.
- P.T. Pharos also has a new requirement of 200 kilograms APAP Micronized valued at \$2,800 for immediate shipment.
- Euro Chemo reported that currently, there are three major Chinese suppliers to the market and these are Wenzhou (Kangle Conler), Anqiu Luan, and Anhui Bayi.

Although they do not represent any Chinese producers, they recently supplied 3 MT to Winwa Medical in Penang.

- Met Albert Chan, managing director of Winwa Medical and he is fully convinced that our APAP is the best available product in the market but the price is simply prohibitive. They use approximately 40 - 50 MT per annum of the standard powder from Wenzhou being supplied by Euro Chemo. Euro Chemo stated that much as they wish to supply our material, the price of above \$6.00 per kilogram is simply too high, considering that their import price from Wenzhou is \$3.80 per kilogram. Albert also indicated that he has used Mallinckrodt material in the past and the product is indeed superior, specially taking into account parameters such as dissolution and disintegration time.
- Winwa also uses 3 MT per annum of Atabay Crystalline material for their capsule product. Material is imported directly at a price of \$4.50 per kilogram.
- Pharmaniaga is requesting for a quotation for 300 MT of Compap Coarse L for a 500 milligram straight APAP tablet they currently produce. Although they prefer our material rather than anybody else's, they are looking a price of \$4.50 per kilogram. Material is to be supplied for a government contract.
- Over dinner with Komagan Kothandapani, purchasing manager of GSK Malaysia, he indicated that their APAP consumption has dramatically increased to at least 500 MT per annum. Approximately 420 MT is imported directly from GSK U.K. (Pangran) and there is an opportunity for at least 70 - 80 MT which they currently import from Rhodia Wuxi in China at a price of \$4.80 per kilogram CNF Sea. Any price higher than this is not acceptable.
- Sales in Australia and New Zealand continue on its steady path. Received these new orders from Ingredients Plus in April 2009:

11910	-	10,000 kgs Paracetamol 4377	-	\$ 81,000
11908	-	10,000 kgs Paracetamol 4377	-	81,000
11980	-	4,000 kgs Paracetamol 4377	-	35,280
12168	-	100 kgs APAP Granular 0057	-	1,366
632	-	5,000 kgs Compap L 0093	-	54,350
Total				\$ 252,996

Bulk Narcotics

Canada

- Ratiopharm have reported problems with Morphine Sulfate degradation products showing up in their finished tablets. Narcotic tech support is working with them on this issue.
- It appears Valeant Canada have been selected by Endo for licencing of their new Oxymorphone product for the Canadian market. Valeant is very anxious to get an agreement signed with us, so that they can announce the deal concurrent with their

quarterly financial report. The first significant volume requirement is expected in 2011, at 90 kilograms. We quoted them USD 8,000, converted to CAD at the current rate, with a currency exchange formula built-in. We also noted that the quote of USD 8,000 is a current price, and is subject to inflationary adjustment for 2011.

- More late deliveries on orders for narcotic products, due to the Regulatory Affairs group of Tyco Healthcare Canada. Valeant has been waiting for over 4 months for delivery of 3 orders of Morphine Sulfate, totaling 35 kilograms. More importantly, we have been delayed by over 1 month on delivery of a new batch of ICH-compliant Hydromorphone HCl for Ethypharm. This was due to a delay in applying for the import permit, by the QPIC in Montreal. Ethypharm orders for impurity standards have also been delayed by several months, due to QPIC issues. The delay in both the API and the impurity standards has set back the development schedule at Ethypharm, for this product which they are developing for Ratiopharm.
- We are working on a CDA for Sandoz Canada, in order to provide them with the open part of our Hydromorphone DMF. Once they have this, they will start work to approve our product for all concentrations of their injectables. We are currently approved only for the low concentration SKUs, due to color issues.
- We are still holding 1 kilogram of Oxymorphone HCl in the Montreal vault for Labopharm. Our agreement called for them to take this product by March 2009, at the latest. We are currently negotiating with them on this issue.

Japan

- This month sales were \$604k, consisting of local sales for Yen19,922k (\$201k) and Japan export sales for \$403k.
- Daiichi-Sankyo took 200 kilograms of Noscapine, code 4887 at the sales price of Yen90,000(\$907) per kilogram. The sales value was Yen18,000k (\$181k).
- Daiichi Fine: No sales this month. 1,000 kilograms of Noscapine, code 4887 arrived in mid April, but it took time to conduct JP test at the authorized laboratory. The test is required before the delivery under the new rule, the revised Pharmaceutical Affairs Law in Japan. The sales will be in May together with another 150 kilograms arriving in early May.
- Hisamitsu: We coped with a weight discrepancy complaint on Fentanyl Citrate, code 1130, providing the second investigation report from St. Louis. The 2,920 grams were shipped through Shin Nippon Yakugyo (SNY), a distributor in December 2008.
- SNY: A problem of missing Export Permit happened again on 200 grams of Fentanyl Alkaloid, code 0129 probably at Memphis airport. It was the third consecutive time for the same customer by FedEx. We agreed to change the airline to JAL to prevent recurrence.
- Hisamitsu expects to receive the 6,552 grams of Fentanyl Citrate, code 1130 immediately for a process validation scheduled in May.
- Teikoku visited our office to discuss a development schedule of the generic Fentanyl patch. Since they plan to submit the ANDA in January 2010, it requires the filing of a Japanese DMF and issue its LOA not later than December.

Latin America

- Astra-Zeneca Argentina sent an order for 250 grams of Fentanyl Citrate (US\$25,000) to ship the end of May.
- Quoted 2 kilograms of Oxycodone HCL to Pfizer Argentina for their cost evaluation of a combo tablet also using our Compap® L 0093.
- Lab Pisa Mexico ordered 118 kilograms of Morphine Sulfate code 1521 (\$118,000) to ship last day in May or first days in June (depends on the DEA and how long it takes to emit our export permit).
- Lab Legrand Colombia ordered 4 kilograms of Hydrocodone Bitartrate (\$18,000) to ship mid May.
- Quoted Cristalia Brazil for their total annual usage of Nalbuphine (7 kilograms) for shipment June-July.
- Denver Farma Argentina ordered 10 kilograms of Meperidine (\$11,000) to ship beginning of May
- Chemilco Guatemala ordered 2 kilograms of Hydrocodone Bitartrate (\$9,000) to ship beginning of May.

Asia/Australia

- Secured new orders for Nalbuphine HCL amounting to \$130,250. Sales of Noscapine continue to suffer as competition from Tehmad (Iran) continues to intensify, with prices at Euro 550 per kilogram. Working on a several new projects such as Bulk Methadone in Taiwan and Malaysia.
- TCM entered a new order for 10 kilograms of Noscapine Base valued at \$10,000. This quantity is earmarked for Vida Laboratories. Fortune also reported their switch from using our material to that of Tehmad's as the price of Euro 550.00 per kilogram is way too low compared to our selling price.
- Eugene Korea entered a new order for 5 kilograms of Nalbuphine HCL at \$9,500 per kilogram for a total value of \$47,500. Material is intended for Daewon Pharmaceuticals, the largest consumer of Nalbuphine HCL in Korea at approximately 10 kilograms per annum.
- A recent shipment of 300 kilograms Propoxyphene HCL to the Taiwan NBCD was deemed unacceptable as it failed to comply with the retest date requirement. Based on the contract, material should have a retest date of 30 months from time of shipment. We did comply to this requirement however, based on the retest date indicated in the COA, material had a retest date of 29 months, or 1 month short of the prescribed 30 months. Further investigation revealed that, as an internal practice, Mallinckrodt sets the retest dates one month prior to its actual retest period. Explained the situation to the NBCD and currently, this issue is being deliberated.
- Received a new order from Kemfar for 300 grams of Fentanyl Base valued at \$21,000. Material is going to be delivered to DSB Pharm, a toll manufacturer for the Taiwan NBCD. Two months ago, we also received an order from the NBCD for 1,000 grams of Fentanyl Base, valued at \$60,000.

- The Taiwan NBCD is seriously evaluating importing bulk Methadone, instead of our Methadose. Their plan is to have the finished product toll-manufactured by a private firm (most likely DSB Pharm). Recently, they inquired about our price for 2 x 160 kilograms of Methadone. Submitted a bid of \$975 per kilogram.
- The Malaysia government has granted manufacturing licenses to four pharmaceutical companies to produce Methadone tablets. Government estimates that up to 700,000 individuals are addicted to heroin but unofficial data indicates that it can be more. Two of these companies are Pharmaniaga and Duopharma.
- Duopharma placed a new order for 5 kilograms of Nalbuphine HCL valued at \$58,750. Current estimates indicate that annual consumption should be in the region of 10 - 15 kilograms. Apart from supplying the local market, Duopharma also exports the ampoules to Southeast Asian markets.
- Duopharma consumes approximately 120 kilograms per annum of Dihydrocodine Bitartrate while Pharmaniaga consumes close to 600 kilograms. Mcfarlan Smith used to supply these two companies but recently, the business went to Salarz Italy with a price of \$540 per kilogram.

Stearates & Phosphates

Canada

- Univar reports that Wyeth Canada switched to Palm Star Magnesium Stearate for all of their requirements. It appears the Palm Star is coming from Street Chemicals, the distributor in Canada for Greven product. Univar are fairly certain that this was a Wyeth Canada decision, and is a departure from Wyeth US.
- Trillium Health Care switched to Greven Magnesium Stearate last fall. However, they have requested 3 lots of 2257 for validation work. It appears we may get this account back, although it is very low volume. Univar are attempting to determine why they have appeared to have changed their minds.
- Lanxess was issued a credit for 3 bulk bags of Calcium Stearate Kosher grade, due to damage which has been confirmed to have happened in our warehouse. All three bags were punctured by the forks of a lift truck.
- McNeil Canada contacted Univar to ask for the "new" 2009 contract pricing on Magnesium Stearate code 2257. Univar were informed that the McNeil agreement has not been signed as yet, and that we will discuss pricing with them after the agreement goes into effect.

Japan

- This month sales were \$43k for Magnesium Stearate, consisting of local sales for Yen2,208k (\$22k) and Japan export sales for \$21k.
- Daiichi-Sankyo took 2,400 pounds of Magnesium Stearate, code 5712 through KYC, a distributor. The sales price was Yen 920 (\$9.42) per pound.
- Invista Fibers China took 6,000 pounds of Magnesium Stearate, code 5774 at the price of \$3.57 per pound for Shanghai plant. Another 6,000 pounds were shipped to Foshan plant this month, but the amount of \$21k was not accounted in April sales.

We will investigate it. Additionally a new order for 6,000 pounds was placed for May shipment to Shanghai. It appears their spandex production is getting recovered. After the shipment, they will accept 8,000 pounds per shipment to fill a 20 feet container for reducing risk of damage during an international transportation.

- Pfizer Dalian China placed a new order for 600 pounds for Magnesium Stearate of code 5712 at the price of \$16.80 per pound. It will be shipped in May.
- Tomoe: 12.6 MT of Manganese Nitrate, code 6175 was shipped in mid April, but the amount of \$101k was not accounted in April sales. We will investigate it.

Latin America

- Farma Venezuela evaluated the sample of Dihydrate Magnesium Stearate code 1729 but the technical department was not able to note any difference in performance but will continue trying it in various other formulations.
- From Mexico we received orders for Magnesium Stearate code 2257 – 6,600 pounds from Gylsa (US\$56,600) and 2,175 pounds from Senosiain (US\$ 18,640) both to ship mid May.
- Merck Mexico has evaluated samples of 2248 in various formulations and now has requested additional material from three different lots for additional stability studies.
- Samples of 2257 sent to Lab Casasco and HLB Pharma in Buenos Aires to help them resolve lubrication issues in some formulations. Lab Bago Argentina ordered 1,350 pounds of 2257 for beginning of May.
- We sent a sample of 5712 to Merck-Sharp-Dohme Mexico for evaluation to use in one of their new formulations.
- Roemmers Uruguay re-ordered 1,200 pounds of Magnesium Stearate 2257 to ship mid June.
- Dow Brazil ordered 5,000 pounds of Magnesium Stearate code 5774 (US\$16,800) to ship last days in April.
- Eli Lilly Mex. ordered 150 kilograms of Aluminum Monostearate 2263 (US\$30,000) to ship beginning of May.
- PISSA Mexico preparing to send us new order for Calcium Stearate and we should receive beginning of May.

Asia/Australia

- Sales of Stearates might be on the decline but Phosphates is growing. Hopefully, sales of Phosphates can somehow offset the continued erosion of Stearate sales.
- Hizon Laboratories entered a new order for 68.04 kilograms (2 x 75 lb drums) valued at \$2,382.
- Unilab Philippines will enter a new order for five (5) drums of Sodium Phosphate valued at \$6,249.90.
- Invista Singapore reported that consumption of Magnesium Stearate for production of Lyrca has reduced considerably as demand has slowed down. Instead of the original 480 bags per shipment, this has been reduced to 320 bags.

Peptides

Canada

- No comment

Japan

- Exenatide: The filing of a Japanese DMF was discussed over a teleconference with Denise Miller, International RA at St. Louis, Kanno-san and Suzuki-san, RA Division and Komai at Covidien Japan. The filing day is scheduled on June 15. As soon as the SMM is translated into Japanese by a contracted consultant on May 8, we will send it Denise for reviewing with Amylin and Lily. The dosage will be imported by Lily Japan under an agreement with Amylin.

Latin America

- No Comment

Asia/Australia

- No Comment

Miscellaneous

Canada

- We continue to have serious issues with Tyco Healthcare Canada on narcotic products service. These issues have put us at considerable competitive disadvantage in the Canadian marketplace, where we already have a significant price disadvantage. Meetings are planned to try and work out a solution.

Japan

- The April sales were \$1,170k, consisting of local sales for Yen74,028k (\$746k at the April exchange rate of Yen99.22 to US dollar) and Japan export sales for \$424k.
- New orders received and pending orders this month amounted to \$2,934k, consisting of Yen203,431k (\$2,050k) for local sales and \$884k for Japan export sales.
- I attended the Mid Year Sales Meeting held in St. Louis from March 30 to April 1.
- Sato-san visited GSK in Australia on April 20 – 23 with Mr. Kikukawa, Assistant Manager, Procurement Department of Daiichi-Sankyo. Nick Litzsinger joined the visit. The purpose was to investigate CPS situations for Noscapine upon Daiichi-Sankyo's request.
- Tachibana-san, Miyabe-san and I attended CPhI Japan held in Tokyo on April 21 - 23.
- QA/RA works: We plan to file Japanese DMF for the following products:
 - Exenatide by June 15
 - Fentanyl Alkaloid by October
 - Noscapine, code 6040/4887 by November

Latin America

- No Comment

Asia/Australia

- Halfway through FY09, YTD sales is slightly still ahead of budget but there is growing concern whether or not this lead can be sustained. The next six months is expected to be a struggle as competition from China APAP producers intensify after a brief lull last year when all chemical plants were ordered shutdown in preparation for the Olympics. We gathered reports from agents, distributors, and customers that supply from China is back in full swing at prices way below ours. Narcotics continue to be steady despite severe price competition on Noscapine, due mainly to increasing sales of other products.