Pink Sheet
pink.pharmamedtechbi.com
July 2017
Pharma intelligence
informa

Consumer Health Focus

OTC Monograph User Fee Goals Document Beats Authorization To Finish Line

MALCOLM SPICER malcolm.spicer@informa.com

FDA is ready with a procedures and performance goals document for an OTC monograph user fee program even though language establishing the program has not been added to legislation pending in Congress to reauthorize the agency's existing drug and medical device user fees.

The agency also on July 27 announced a webinar scheduled for Aug. 23 to discuss the document and to update industry stakeholders on progress in the initiative to consider user fees to support FDA's monograph program, which kicked off with a May 2016 Federal Register notice.

FDA Commissioner Scott Gottlieb has said FDA "reasonably" expects timely reauthorization of the drug and medical device user fee programs by Congress before the end of fiscal 2017, Sept. 30. *(Also see "FDA Gives Congress Reprieve On Deadline For Passing User Fee Bill" - Pink Sheet, 25 Jul, 2017.)*

But while FDA stands at the ready for implementation, there are no clear signs from Congress about whether OTC provisions will also be added. Still, the Consumer Healthcare Products Association considers "OTC monograph reform is still very much in play," says Marc Schloss, the trade group's head of federal affairs. Schloss added that CHPA is "encouraged by the bipartisan momentum we've seen behind OTC monograph reform in both the House and Senate."

FDA notes early in the document that implementation of "Over-the-Counter Monograph User Fee Act" (OMUFA) procedures and other requirements, and acceptance of monograph proposals under the act starting Oct. 1, would come only "if the program is enacted by Congress."

FDA's proposed guidelines for submitting monograph change proposals, for its application and review deadlines, for adding staff to the agency's monograph review team and for other components of the process and its costs track with discussion drafts of legislation authored by Sens. Johnny Isakson, R-GA, and Bob Casey, D-PA. *(Also see "OTC Monograph User Fees Totaling $22m To $34m Floated In Senate Discussion Draft" - Pink Sheet, 19 May, 2017.)*

The senators also proposed raising $22m to $34m through the user fees, primarily from facility registrations, and a two-tier review system recommended by FDA and the industry *(see boxes p3)*.

In addition to timelines and submission standards for OMUFA, FDA includes a schedule for developing and launching an information technology platform accessible to the industry and the public that will track progress on proposals and on the agency's reviews.

"Prior to OMUFA, no IT platform exists for the monograph, a lack with greatly hampers review efficiency," the Center for Drug Evaluation and Research states in the document.

CDER says it will implement the IT platform, which agency officials and industry stakeholders call a "dashboard," by October 2019, a year after it commits to developing specifications and awarding a contract for the project.

The center also includes in the manual a plan for launching an IT portal specifically for receiving monograph submissions, or "OTC Monograph Order Requests" (OMORs), in 2022. FDA will issue an RFP for the platform for receiving electronic submissions, archiving review work and generating reports by February 2019, award a contract within two months after that and establish requirements for the portal by April 2020.

FDA says OMORs must be submitted electronically using content and format recommendations from its guidance on submitting OTC sunscreen monograph proposals as those recommendations, although developed for sunscreen drug products, are "generally applicable to all monograph submissions." *(Also see "Sunscreen Industry Asks FDA For Flexibility Despite Guidances' Rigidity" - Pink Sheet, 28 Nov, 2016.)*

CDER said it will clarify the sunscreen-specific guidance's applicability across monograph drugs in an updated draft

EDITORS NOTE

Since we published these articles, Congress passed legislation reauthorizing FDA agency's existing drug and medical device user fees without adding provisions creating an OTC monograph user fee program. The Pink Sheet will publish additional articles that bring this topic up to date along with our continuing coverage of the pharma industry's consumer health products sector.

CONTINUED ON PAGE 3

Pink Sheet
Pharma intelligence | informa

JULY 2017

Our selection of **Consumer Health** content from the past month includes some of our most-viewed articles online and editors' picks of top issues across the Consumer Health sector. References to related content in stories are live links: click to read more.

Please visit **pink.pharmamedtechbi.com/consumer-drugs** for full access to our comprehensive, up-to-the-minute news coverage and analysis.

EDITORIAL OFFICE
52 Vanderbilt Avenue, 11th Floor
New York, NY 10017
phone 240-221-4500, fax 240-221-2561

CUSTOMER CARE
1-888-670-8900 or 1-908-547-2200
fax 646-666-9878
clientservices@pharmamedtechbi.com

CONTINUED FROM COVER

guidance by April 2019 and will issue a final guidance by October 2020.

CLOCK TICKS ON REAUTHORIZING USER FEES

FDA published the documents without provisions for the OTC monograph program included in the House and Senate bills for a five-year reauthorization of the agency's drug and medical device user fee programs, H.R. 3420 and S. 934. Both bills are open to be amended with H.R. 3420 passing the House and S. 934 moving from committee deliberations to the Senate floor.

The current authorization expires at the end of fiscal 2017, Sept. 30. CHPA targeted user fee reauthorization legislation as a likely vehicle for adding a monograph user fee program when the industry and FDA began discussing details for a program in 2016. *(Also see "OTC Monograph 'Disruption' Could Ride On PDUFA Reauthorization's Back" - Pink Sheet, 21 Mar, 2016.)*

With its user fee authorization ending in little more than a month, FDA typically would distribute reduction-in-force notices on Aug. 1 to employees who could lose their jobs if legislation extending the programs another five years is not enacted by Oct. 1. Even so, FDA must tell employees supported by user fee revenue at least 60 days in advance that they could be let go.

However, Gottlieb on July 24 told agency employees that it would not send RIF notices for user fee-supported staffing given the agency's expectation of timely passage.

With congressional authorization, FDA launched the monograph program in 1972 as a system for allowing OTC ingredients GRASE for their intended uses to remain available and as a process for proposing additions of more ingredients or indications. A monograph essentially offers a menu of ingredients and formulations that can be used in drugs for certain indications. *(Also see "FDA Asks Whether User Fees Will Repair OTC Monograph Process" - Pink Sheet, 10 May, 2016.)*

However, the program has been stalled for much of its 45 years and FDA and industry stakeholders identified reforming the program as a nonprescription sector priority well before they began negotiations on a proposal. Any addition or other change, no matter how small or how urgently needed, requires a formal rulemaking, a longer and more arduous process than FDA's procedures for reviewing and deciding whether to approve new prescription drugs, or nonprescription drugs containing ingredients previously available Rx-only. In fact, during his confirmation hearing in the Senate, Gottlieb said modernizing the monograph system needed "immediate action" more than 10 years ago. *(Also see "OTC Monograph Woes No Surprise To FDA Commissioner Nominee Gottlieb" - Pink Sheet, 5 Apr, 2017.)*

TIER 1 GETS MOST OMORS

The OMUFA document says most OMORs will be tier 1, that is, proposals for adding to monographs that already include one or more ingredients found to be generally regarded as safe and effective:

- an ingredient, dose or concentration;
- an indication that applies to one or more of a monograph's ingredients already found to be GRASE;
- a fixed-dose combination of ingredients;
- a test method that applies to one or more of a monograph's GRASE ingredients;
- a route of administration that applies to one or more of a monograph's GRASE ingredients;
- a therapeutic category, with each ingredient proposed for a new category covered in separate OMORs.

FDA would have authority to request human clinical trials for tier 1 requests. If it does, the manufacturer would be eligible for up to two-years market exclusivity, similar to the component of the agency's rule for Rx-to-OTC switch applications that allows three years of exclusivity for proposals that must include clinical trial data.

TIER 2 LIMITED BUT OPEN TO CHANGE

Tier 2 OMORs will propose:

- reordering existing information in Drug Facts labels;
- standardizing the concentration or dose of a specific finalized ingredient within a finalized monograph;
- changing ingredient nomenclature to align with a standards-setting organization;
- adding an interchangeable term;
- modifying existing Drug Facts label directions for use to be consistent with a final order or guidance pair on minor dosage form changes;
- adding either required or optional information under the "Other Information" section of Drug Facts labeling.

Decisions on whether a proposed OMOR meets any tier 2 criteria will be made by the program's review division after receipt of an OMOR. Noting the potential program's groundbreaking nature for its OTC reviews, the agency said that "other specific items may be added by FDA later as FDA gains experience" with tier 2.

Clock Ticks On Adding OTC Monograph Reform To FDA User Fees Bill

MALCOLM SPICER malcolm.spicer@informa.com

Time is running short and competing issues are stacking high for adding OTC monograph reform and user fees to legislation reauthorizing FDA's existing user fee programs for another five years.

With Congress leaving Washington during the week of Independence Day and for much of August, few days remain for House and Senate committees to consider adding to language from Sens. Johnny Isakson, R-GA, and Ben Casey's, D-PA, OTC discussion draft to the pending reauthorization legislation – H.R. 2340 and S. 934.

Failure to reauthorize the user fee programs agreements by late July would prompt FDA to send layoff notices to more than 5,000 employees to notify them that they may lose their jobs when the federal fiscal year ends Sept. 30.

The Consumer Healthcare Products Association, which negotiated with FDA on terms of the monograph proposal included in the draft, is joined by medical and advocacy groups the American Academy of Pediatrics, Society for Maternal-Fetal Medicine, American Public Health Association, March of Dimes, Pew Charitable Trusts and National Association of County and City Health Officials in urging members of Congress to include the changes in the user fee reauthorization legislation.

The groups continued urging passage in their latest letter, dated June 14, to Isakson, Casey and Senate Health, Education Labor and Pensions Committee Chairman Lamar Alexander, R-TN, and ranking member Patty Murray, D-WA. They say "monograph reform can and should be included within the Food and Drug Administration Reauthorization Act (FDARA) of 2017," and FDA, the pharma industry "and public health stakeholders are in clear consensus that OTC drug regulation reform is long overdue and should be a top priority for this Congress."

However, FDA's OTC monograph problems likely are not a priority for Congress currently. An overhaul of the Affordable Act – either repeal and replace or enacting changes – is the health care-related topic dominating Congress members' attention. Imposing drug-pricing standards has emerged as one contentious topic in discussions on legislation targeting changing or repealing the ACA. *(Also see "Drug Pricing Hearing In Senate Postponed, Handing Innovators Another Victory" - Pink Sheet, 29 Jun, 2017.)*

When the House and Senate resume meeting July 10, additional hearings and ongoing investigations into Russian hacking into US elections and on potential illegal collaboration with Russian officials and businesses by people associated with President Trump's campaign along with work on developing and approving FY 2018 appropriations for FDA and other federal agencies will dominate members' time.

Doing anything more than passing FDARA only to continue FDA's existing user fees programs could be too much to expect, says Kurt Karst, a food and drug lawyer following FDARA discussions.

"At some point it will come down to, just get it out," said Karst, a director at Hyman, Phelps & McNamara P.C. in Washington.

Backing from CHPA and its allies is crucial to any chance for adding the monograph reform language to FDARA, and Congress is capable of surprises.

"I certainly think [CHPA's lobbying] helps. But the timing doesn't help," Karst added in an interview.

CHPA is keeping its eye on the goal. "We are optimistic that OTC Monograph reform will move forward along with the FDA Reauthorization Act," the group told the Pink Sheet.

Pew, the lead in contact with Congress among the groups backing monograph reform, points out making the changes has bipartisan support. "We have confidence that Congress will act before the end of 2017 to address outdated and inefficient OTC regulation under the current monograph system," said Kirsten Moore, PEW's health care products project director.

Isakson and Casey propose that manufacturers have two tracks for proposing changes to OTC products marketed under the monograph system: one for adding new medical conditions treated by the ingredients, which would be eligible for exclusivity when clinical trials are required, and another for most other types of changes. The senators in early May released an initial discussion draft and in early June distributed another version that had been cleared of notes and questions. *(Also see "OTC Monograph Reform Proposal*

Offers Two-Tier Approach" - Pink Sheet, 30 May, 2017.)

Similar to the Sunscreen Innovation Act Congress passed in 2015 to encourage adding new ingredients to the OTC sunscreen monograph, the discussion draft proposes deadlines for FDA reviews for the other monograph categories.

Total annual user fees of $22m to $34m from OTC manufacturers – primarily from facility registrations – are among the draft's proposals. Fees would also be raised when companies request changes via the monograph system. *(Also see "OTC Monograph User Fees Up To $34M Floated In Senate Discussion Draft" - Pink Sheet, 30 May, 2017.)*

FDA launched the monograph program, following congressional authorization, in 1972 as a system for allowing OTC ingredients generally recognized as safe and effective for their intended uses to remain available and for offering drug firms and other parties, including the agency, a process for proposing additions of more ingredients or indications. However, the program has been stalled for much of its 45 years and FDA and industry stakeholders identified reforming the program as a nonprescription sector priority well before they began negotiations on a proposal in June 2016. *(Also see "'Real Challenge' To Improve OTC Monograph Program Without User Fees – FDA" - Pink Sheet, 13 Jun, 2016.)*

OTC Switch Interest Cooled By Study Costs To Update Safety Data

EILEEN FRANCIS eileen.francis@informa.com

Pharmaceutical firms get cold feet about potential OTC switches when they consider the costs for studies to update safety data for an ingredient, suggests Laura Mahecha, a health care market consultant for research firm Kline & Co.

During a June 27 webinar, "Key Issues Trending in the US OTC Market," Mahecha noted that with safety "paramount for switch approval," data from a drug ingredient's initial approval for Rx sales might not support allowing OTC sales.

"What we've been hearing in part of our research in the last six months or so, is that many of the switch candidates have been on the prescription market for 10 or more years, so the original safety and efficacy data done to support Rx approval was done over 15 years ago, when measurement tools and technology was very much underdeveloped compared to what we have today," she said.

"So, that's making companies have to either re-analyze old data, or most of the time conduct new safety studies on these medications, and that's proving to be an additional risk factor and cost burden for switch sponsors," added Mahecha, an independent consultant in the consumer product space.

The presentation provided a snapshot into three Kline reports, including "Rx-to-OTC Switch Forecast USA," which forecasts the opportunities and challenges for switches through 2022 and will be available in the fourth quarter.

OTC ADDS LAYER TO FDA SAFETY DECISION

FDA encourages switch applications, particularly for ingredients indicated for chronic conditions including high cholesterol, high blood pressure, diabetes and asthma, but Mahecha noted drug firms also are put off by what she called a "higher bar" for approval FDA imposes on OTC switches compared to Rx applications.

Prescription ingredients are tested extensively before new drug applications or abbreviated or supplemental NDAs are submitted; many do not reach FDA when studies show safety or efficacy problems; and they are subjected to lengthy reviews by the Center for Drug Evaluation and Research, often including input from advisory committees, before the agency reaches a decision on approval. Generics and biosimilars of innovative Rx ingredients also go through costly research before applications are submitted and CDER begins its extensive reviews.

OTC switch NDAs have the benefit of following the research and other work conducted for an Rx ingredient's application, but also must convince FDA of an additional safety point. OTC approval requires showing that a product is safe for its indicated use without a health care professional's intervention into a consumer's decision on selecting the product, which entails consumers accurately self-selecting whether they need to use a drug available without prescription and adhering to follow-up directions to determine if they should continue treatment with the product. *(Also see "Pharma Firm ISO OTC Switch Partner; NDA Experience, Resources Needed" - Pink Sheet, 24 Oct, 2016.)*

Concerns about whether consumers will accurately self-select and follow directions when continuing treatment is needed were behind FDA's rejection of three switch proposals by **Merck & Co. Inc.** for a statin ingredient to treat high cholesterol and behind Pfizer Inc.'s decision in 2015 to stop its research to support a switch proposal for a different statin. *(Also see "Light Still On For Switches After Pfizer Pulls Plug On OTC Lipitor" - Pink Sheet, 3 Aug, 2015.)*

For products that are first-in-class for an OTC indication, have a novel mechanism of action or present unique concerns, FDA typically asks an advisory committee to review and recommend whether to approve the application.

Companies may be asked to submit consumer behavior research studies for label comprehension, self-selection and actual use. Although the studies are not always required for a switch, FDA more frequently is asking for consumer behavior research information as meaningful data on wheth-

er a drug will be used safely and effectively under OTC labeling. *(Also see "Naloxone Talk Sheds Light On Switch Research Future" - Pink Sheet, 7 Jan, 2013.)*

In addition to safety and efficacy data, including adverse events, for the original prescription drug in switch sponsors' NDAs or ANDAs, CDER occasionally will ask for information on OTC use of the ingredient in other countries.

During the webinar, Mahecha identified safety challenges for switch categories analyzed in the Kline report *(see table below)*.

"Our switch research is looking at these categories, but there's specific safety concerns with each one of these, even when they are in existing categories," she said.

For example, in the nasal spray allergy category, companies must tackle the potential for growth suppression in children from systemic absorption of intranasal steroids. In digestive health products, companies face concerns over possible side effects of long-term use off proton pump inhibitors, including risks of bone fracture and renal issues.

The Consumer Healthcare Products Association has said the concern is only relevant to prescription PPIs. *(Also see "Petition Seeks OTC PPI Warning On Cancer Risk From Persistent Heartburn" - Pink Sheet, 2 May, 2017.)*

Firms looking to switch an Rx sleeping aid must study its addiction potential as an OTC, while marketers of topical pain relief candidate drugs must analyze cardiovascular concerns from systemic absorption of topical NSAIDs, Mahecha noted.

Meeting those requirements often comes at a high cost for firms, which weigh the spending against the revenues they estimate from sales of the potential OTC product. A factor in those calculations is whether an OTC switch would launch with three-year market exclusivity, which FDA may allow when clinical trials are part of a switch application. Switches without market exclusivity, or most of them, face generic competition as soon as competing firms receive FDA approval for their products.

Despite those challenges, Kline predicts switches and other factors will help drive growth of the overall OTC market at a compounded annual growth rate of 2.2% and for sales of switched products to grow at a compounded annual growth rate of 5% through 2018.

Switches in 2017 have included **GlaxoSmithKline PLC**'s introduction of *Flonase Sensimist* Allergy Relief (fluticasone furoate) in January, and in February **Sanofi**'s launch of *Xyzal Allergy* (levocetirizine dihydrochloride) in February and **Galderma Laboratories L.P.**'s debut of *Differin* Gel (adapalene), the first OTC acne ingredient approved in the US in 20 years. *(Also see "Differin Gel Enters Changed Marketplace Since Last OTC Acne Drug Approval" - Pink Sheet, 22 Aug, 2016.)*

Switch Categories' Safety Questions

CATEGORY (INDICATION)	FDA'S SAFETY CONCERN
Acne	Teratogenicity from systemic absorption of topical retinoids
Allergy	Growth suppression from systemic absorption of intranasal steroids
Benign prostatic hyperplasia	Masking of prostate cancer with alpha blockers
Digestive products	Long-term use of PPIs
Erectile dysfunction	Cardiovascular risk with PDE5 inhibitors
Migraine	Cardiovascular risk with triptans
Overactive bladder	Masking of bladder cancer, kidney problems and prostate cancer in men with symptoms similar to OAB
Sleeping aids	Addiction potential
Skin rash/eczema	Growth suppression from systemic absorption of topical steroids
Topical pain relievers	Cardiovascular risk from systemic absorption of topical NSAIDs

Source: Kline & Co.

WAITING ON NSURE

FDA has acknowledged firms see a barrier to switch and are skeptical of options to ensure safe use of their products, though those options – such as developing extra-label information, instructions or questions that can be accessed online – have been floated by the agency and companies alike. *(Also see "FDA's OTC Naloxone Study Is A Starting Point For Other Switches, Not A Roadmap" - Pink Sheet, 16 May, 2017.)*

FDA began the Nonprescription Drug Safe Use Regulatory Expansion initiative in 2012 to look at potential changes in the application process so sponsors could propose novel switches, including ways to expand safe use communications beyond the drug facts label. *(Also see "Room For Innovative Switches Could Lurk In Existing FDA Framework" - Pink Sheet, 29 Oct, 2014.)*

In 2015, Mahecha acknowledged that despite the NSURE initiative and a "favorable" regulatory environment for the products, the switch landscape has been "quiet." At the time, she noted the high costs of making a switch – including the product's application and then it's marketing and advertising – as one factor slowing the pace of new switches. *(Also see "Merck Silence On OTC Singulair Speaks Volumes On Switch Outlook" - Pink Sheet, 10 Dec, 2015.)*

She also noted Kline's FutureView Forecasting Model online tool that uses basic drug description ajnd information on manufacturers and countries to calculate estimates of a "probability of switch" and post-switch sales.

GSK Trims Nutritional Drink Lines, Wants All Of Its Consumer JV Pie

MALCOLM SPICER malcolm.spicer@informa.com

GlaxoSmithKline PLC's short-term approach for consumer health is less is more with planned sales of two UK brands, but the long-term is all about more as it anticipates buying out **Novartis AG**'s interest in the two companies' OTC drug and nutritional products joint venture.

With its fiscal 2017 second-quarter earnings report on July 26, the UK firm made clear it's ready to become sole owner of the JV, **GlaxoSmithKline Consumer Healthcare LP**. It also noted that divesting UK brands *Horlicks* and *MaxiNutrition* are among its steps toward improving its consumer business margins.

Glaxo reported its consumer health sales, including Novartis' consumer products marketed by the JV, grew 10% to £1.9bn ($2.5bn) on an adjusted rate, though were flat on a constant foreign exchange rate.

The firm says pain relief and oral care lines, including US brands *Excedrin* (acetaminophen) analgesics and *Sensodyne* toothpastes, drove sales but were offset by weaker US allergy product sales and a broader slowdown in other categories, particularly in markets outside Europe and the US.

GSK Consumer's overall sales for pain relief and other products in its wellness category were up 9%, or flat on constant currency, to £925m ($1.2bn); up 13% (3% on constant currency) to $792.9m for its oral care products; up 3% (down 8%) to $216.2m for its nutritionals; and up 8% (down 1%) to $205.8m for its skin care lines.

US sales held back overall consumer health grow with a flat quarter (off 8% on constant currency) at $563.6m as European market sales grew 16% (7%) to $758.9m and international market sales increased 10% (flat) to $711.7.

CEO Emma Walmsley sees the consumer business performance as a step in a process of making the unit as much a global business as Glaxo's pharmaceuticals and vaccines.

"All three businesses now benefit from a global footprint capable of accessing growth in established and emerging markets," Walmsley, who previously headed GSK's consumer operations, said during a same-day briefing with analysts. *(Also see "Consumer Business Reliable And Right At Home At GlaxoSmithKline" - Pink Sheet, 27 Apr, 2017.)*

Already global, the consumer business is not all GSK's. It has been the majority (63.5%) owner and operator of the JV since its deal with Novartis closed in 2015. The agreement gives Novartis a 20-year put option that allows it to sell its share after three years, which will come in March 2018, with Glaxo getting first shot at the stake. *(Also see "Glaxo In Charge, And The World Is GSK/Novartis Consumer Product JV's Oyster" - Pink Sheet, 8 Jun, 2015.)*

Eight months before Novartis can unload its share, analysts want to gauge Glaxo's plans, and the firm was clear on its interest and its confidence.

"We've been very clear we would like to acquire the rest of the business as and when they decide to exercise. We're very comfortable we can fund it exactly how we choose to fund it," Walmsley said.

She also noted that for consumer and GSK's other businesses, "if additional investment is required to maximize full value of a particular asset we will act with the long-term interest of the group's performance in mind."

In addition to investing, Glaxo is divesting to help grow its consumer business. It announced July 19 that it intends to sell its Horlicks nutritional drink mix and MaxiNutrition sports supplement lines in the UK, is considering options on selling other "smaller non-core nutrition brands" and plans to close a Horlicks manufacturing site in Slough, England.

Those consumer health changes are among the trimmings that Glaxo expects to improve the business' margins at least 20% by 2020. During the briefing, Chief Financial Officer Simon Dingemans noted other changes as well as sales growth are needed to reach the goal.

"We are seeing a marked slowdown in consumer market growth and that's clear in our own numbers. While growth has slowed we believe we have a portfolio capable of responding to this challenge," Dingemans said.

C&D Oral Care Marketing Flows To Professionals Through WaterPik

EILEEN FRANCIS eileen.francis@informa.com

Church & Dwight Co. Inc.'s $1bn acquisition of **Water Pik Inc.** opens a door for promoting its oral care brands with dental professionals and sets up *WaterPik* water flossers for a jump in international sales.

While C&D already markets oral care lines and has a larger domestic retail presence and international footprint, Water Pik leverages its "strong reputation" among US professionals to market its water flosser line more than 40,000 dental care providers annually and build 90% market share in the powered flosser category, said C&D President and CEO Matthew Thomas Farrell during a July 17 briefing with analysts.

C&D announced its agreement to acquire Fort Collins, Colo.-based Water Pik, which also markets the top US shower head line under the same brand, from private equity firm **MidOcean Partners** on July 16.

C&D, with an oral care business including the *Arm & Hammer* toothpaste line, *Spinbrush* battery-operated toothbrushes, the top selling battery-operated toothbrush, and *Orajel* oral analgesics, also a category leader, says water flosser is a fast-growing category on trends of more older consumers reporting gum disease, oral care awareness across all demographics and expansion of the middle class in emerging markets.

Dental professionals' recommendations to patients are a key component of oral care product sales, and **Colgate-Palmolive Co.** has dominated the channel in recent years through consumer outreach programs with professionals. In 2009, Colgate established the *Colgate* Oral Health Advisory Board, which offers educational benefits exclusively for the dental hygienist.

WaterPik sales grew 10% over the past few years as household penetration increased from around 17% in 2015 to 19% currently, with marketing spending at about 10% of sales, Farrell said. Water Pik has "done a super job with its own professional network" as well as also TV ads, he said,

Farrell added that water flossing has been shown in roughly 65 published clinical studies to reduce inflammation and plaque that lead to gum disease. "These facts are well known by dental professionals. Sixty percent of consumers who buy a WaterPik water flosser do so because a dentist or a hygienist recommended it to them," he said.

Asked if C&D will have opportunities to cross-sell its other oral care brands with WaterPik products, including a tooth whitening strip, Farrell said cross-promotions hold promise even though the practice did not factor in the consumer health, personal and household care firm's forecasts for the acquisition's impact on its revenues.

"We agree that should bode well for our oral care business going forward. By having access to the dental professionals, we now have a way in that we didn't have before," he said.

APPLY US STRATEGY ABROAD

During a June investors' conference in Paris, Farrell noted C&D was extending its reach into seven global markets, including Brazil, Canada, Mexico and Europe, with offices opened in 2016 in Panama and Singapore as hubs for extending distribution of its products in Latin American and Asian markets. He also noted that through acquisitions of brands or companies, C&D will double the size of its international business, reaching $1bn in annual sales outside the US. *(Also see "Church & Dwight Hooks Future Growth To International And Internet Sales" - Pink Sheet, 13 Jun, 2017.)*

C&D expects 4% sustainable growth of the business going forward, compared to evergreen growth of 3% in recent years. Growth largely will depend on how well it grows WaterPik product sales abroad. Water flosser sales are biggest in the US, where the benefits are better known among consumers and dental professionals.

Internationally, C&D must set up a "similar process" in reaching dental professionals "and that takes a little bit of time," Farrell said.

In addition to promoting products through professionals, C&D needs to build awareness of water flossing outside the US. "Once it's in place, it's a sustainable driver of growth. So, we're going to have to pick a few countries where we're going to have to go after that," Farrell said.

Ultimately, C&D hopes to "replicate what Water Pik has been able to pull off in the United States," he added.

C&D's 2016 international sales grew 4.8% to $525.2m, according to its year-end report earlier this year. In the first quarter, the firm's international consumer product sales soared 12.3% to $143.1m and consumer product domestic sales experienced a 1.8% increase in the January-March period to $659.7m *(Also see "International Drives C&D Sales, NPA On WIC, Recalls: Health And Wellness Industry News" - Pink Sheet, 8 May, 2017.)*

$10M SYNERGIES BY 2019

C&D expects $10m in operating synergies from the deal by 2019, primarily from incorpo-

BUYING A CONSUMER HEALTH 'CATEGORY'

Water flossers account for 70% of Water Pik's sales, $265m for the 12-month period through June, and the US represents 80% of the total, with the remainder spread across 80 countries.

In the US, the only "appreciable" competition is **Koninklijke Philips NV**'s *Phillips Sonicare*, which is an air flosser, Farrell noted. "It is a category in a way, the WaterPik product," he said.

Water flossers are devices made with a motor and pump that release a stream of pressurized water to flow from the tip of a reservoir and force plaque, bacteria and food particles away from teeth. FDA regulates the products as class one oral devices, which do not require pre-market approval.

rating WaterPik products in its supply chain. The Ewing, N.J.-based firm says it expects the deal, subject to regulatory approval and other conditions, to close before October.

C&D said the deal, structured as a stock purchase financed with debt, is expected to be neutral to its 2017 earnings per share, inclusive of transition costs, acquisition-related expenses, interest expense and intangible amortization expense.

It expects 2018 adjusted EPS growth around 9%, driven by 7% growth of the existing business plus 3% accretion from the Water Pik acquisition but "offset by a 1% drag from onetime transaction costs.

The Water Pik acquisition is consistent with C&D's strategy of acquiring brands that rank top one or two in a category. Farrell noted the WaterPik showerheads brand is a category leader with 27% share.

Market analysts see the deal as another, and not last in a series of revenue-building acquisitions by C&D.

In a July 17 research report, Morningstar's Erin Lash estimates WaterPik products will add around 7% to C&D total sales. "We doubt the firm's appetite for deals has waned and anticipate C&D's focus will primarily center on smaller, bolt-on deals that are unlikely to move the needle on our valuation," she said.

At Jefferies, analysts said the deal a "good fit/fair price" move that "makes good, strategic sense for" C&D, which "still has room to do deals between now and 2019."

BMO Capital Markets analyst Shannon Coyne has a similar view. "We believe CHD still has buying power of [around] $1b for additional acquisitions without impacting its credit rating," she stated in a report.

FTC Review Of Colgate Optic White Claims Delays Class Action Complaint

EILEEN FRANCIS eileen.francis@informa.com

A Federal Trade Commission review of *Colgate Optic White* toothpaste "deeply whitens" claims delays a class actioncomplaint against **Colgate-Palmolive Co.,** but compliance with FDA regulations for the product doesn't pre-empt challenging the claims under state law, says a federal judge.

A June 23 decision in the US District Court for the Southern District of New York requires the firm to provide updates every six months on progress in FTC's review of ad claims for Optic White. A commission spokesman declined to comment on the review's status.

The complaint, filed in May 2016, followed National Advertising Division reviews that challenged Colgate on the whitening claims. In a 2012 review on a challenge by **Procter & Gamble Co.**, the Council of Better Business Bureaus' industry self-regulation arm recommended Colgate avoid attributing whitening improvement to the peroxide ingredient and to modify its ad claims, but the firm did not comply with the advice.

When NAD again evaluated the whitening claims in a 2014 compliance inquiry, Colgate claimed to have reformulated Optic White and said it had new evidence to support claims about the toothpaste's intrinsic whitening capabilities.

NAD argued the reformulations did not change the amount of hydrogen peroxide in the product and did not address the toothpaste's ability to provide whitening benefits below the tooth surface. When Colgate again refused to comply with NAD's recommendations, NAD lawyers referred the case to FTC in July 2014. *(Also see "Colgate's Second NAD Swing To Support Optic White Claim Lands At FTC" - Pink Sheet, 28 Jul, 2014.)*

US District Judge Cathy Seibel, in her decision responding to Colgate's Jan. 18 motion to dismiss, said staying rather than dismissing the complaint will allow the plaintiff – a New York woman represented by Kirkland & Ellis LLP in New York – to decide whether to continue following FTC's decision.

Filed in May 2016, the putative class action alleges that the consumer bought Optic White based on claims that the product could go beyond surface stains to deeply whiten teeth, as claimed on packaging and in advertising.

Colgate markets Optic White and Optic White Platinum toothpastes in multiple varieties and formulates both with 1% hydrogen peroxide, to which it attributed the products' deep clean capabilities that go beyond removing surface stains.

The plaintiff argued that Optic White cannot go beyond surface stains to deeply whiten teeth because peroxide in toothpaste does not function as whitening agent on intrinsic stains.

PRIMARY JURISDICTION CRITERIA MET

Siebel's decision noted primary jurisdiction doctrine, judicial deference to a regulatory agency with specific oversight of a relevant issue if certain criteria apply.

She said Colgate "is correct that because 'the FTC is currently in the process of reviewing the validity of the exact claims at issue in this litigation,' the risk that it would be subjected to inconsistent rulings is particularly high."

Colgate also has asked courts in California and New York to apply primary jurisdiction doctrine to delay two class action complaints against "natural" claims for its *Tom's of Maine* toothpaste until FDA weighs in on whether it will impose a regulatory definition for natural. *(Also see "Oral Care, Topical Product 'Natural' Claims Paint Bullseye For Class Action" - Pink Sheet, 1 Nov, 2016.)*

Seibel noted in her decision that primary jurisdiction's central aim is to designate to courts or to agencies initial decision-making responsibility on litigation that alleges violations of regulations and to ensure they do not work at "cross-purposes."

Colgate met three of the four factors for determining whether primary jurisdiction is appropriate, according to the decision.

Seibel said the first factor – whether the litigation was better considered "within the conventional experience of judges" or the "technical or policy considerations within the agency's field of expertise" – was "neutralized." On one hand, the case falls within judges' conventional experience, but Seibel said the court is presumably less well-equipped than FTC to determine as a matter of science whether the whitening capabilities of Optic White are valid and supported.

However, the judge found Colgate's argument met the second factor – the issue falls within the discretion of FTC; and the third factor – a risk for inconsistent rulings if both

'BEYOND SURFACE' RED WINE-DIP TEST

Claiming the Optic White product she purchased did not deeply whiten her teeth or whiten intrinsic stains, the class action plaintiff cited three violations of New York law. Her lawyers filed the suit on behalf of all US consumers who purchased Optic White since October 2013 or Optic White Platinum since February 2014.

Packaging for the products includes the claims:

- "Goes beyond surface stain removal to deeply whiten teeth."
- "Deeply whiten."
- Optic White toothpaste is clinically proven to whiten teeth with peroxide [and] goes beyond surface stains unlike ordinary toothpastes."
- "Deeply whitens more than 3 shades."

TV advertising also misled consumers, the complaint alleges. One commercial depicted a shell "made of calcium that can absorb stains like teeth" that is dipped in red wine for 10 hours. The ad illustrated the toothpaste's "supposed deeply whitening capabilities" by comparing one side of the shell, which is brushed with regular toothpaste and remains dark, to the other, which was brushed with Optic White and appears white.

Text beneath the shell states "Colgate Optic White can penetrate to work below the tooth's surface." Another spot featured the text, "Unlike the leading whitening toothpaste, Colgate Optic White toothpaste beyond surface stains to deeply whiten teeth."

the litigation and FTC's review move forward at the same time. Additionally, FTC's ongoing review confirms the fourth factor – an administrative agency's prior application to claims in question.

"I find it appropriate to allow the FTC to address the issues raised here in the first instance. Further, given the FTC's pending investigation into the very claims at the heart of the Plaintiff's case, the advantage of applications of the doctrine, in light of the agency's expertise … and the progress it has made, outweigh the potential for undue delay," Seibel wrote.

She added that while invoking primary jurisdiction "may theoretically delay resolution of plaintiff's claims, the prospect of significant delay is reduced by the fact that the FTC has already been investigating this matter for more than two years."

NO PRE-EMPTION BY FEDERAL OVERSIGHT

Colgate argued that FDA has "broad" regulation over toothpastes, the majority of which are marketed as OTC drugs with some formulations available only Rx, including requiring pre-market determination that a drug is generally recognized as safe and effective for the indicated use.

The company also identifies federal requirements it contends specifically address its whitening products: FDA's final monograph for anticaries OTC drugs, a 1985 nonfinal version of the anticaries monograph that addressed toothpastes' whitening effects, and the denial of an American Dental Association citizen petition requesting that peroxide-containing tooth whiteners be used with the consultation of a dentist.

However, Seibel dismissed each argument. She noted that the final anticaries monograph provides that only three active ingredients meet its conditions – sodium fluoride, sodium monofluorophosphate and stannous fluoride. "There is nothing in the monograph regarding whitening toothpastes or products," she said.

While Colgate argued that the previous nonfinal version of the anticaries monograph specifically addressed whitening effects, Seibel said the draft only discussed whether a warning is appropriate regarding temporary surface teeth staining caused by products containing stannous fluoride and not stains "ostensibly ameliorated by hydrogen peroxide."

"It does not include any discussion of hydrogen peroxide, much less a discussion of the 'whitening effects of toothpastes' as defendant claims," she said.

Seibel said that the FDA's denial of ADA's petition "does not, as defendant claims, address the substance of any representations about the whitening effect of peroxide-containing products." *(Also see "Consumer Tooth Whiteners Belong In Homes; FDA Denies ADA Petition For Drug Status" - Pink Sheet, 28 Apr, 2014.)*

Also in support of its pre-emption argument, Colgate pointed to Southern District of New York precedent in the 2014 Bowling v. Johnson & Johnson decision, which found litigation challenging J&J's claims that its *Listerine* mouthwash containing sodium fluoride "restores enamel" was pre-empted due to FDA regulatory oversight. The court said while FDA did not consider the exact language used by J&J, it addressed the substance of the claims at issue.

However, Seibel said the Bowling ruling differs from Colgate's argument. "Unlike Bowling, where the FDA had addressed the substance of the plaintiff's claims, plaintiff here challenges defendant's claims regarding a subject the FDA did not consider in its rulemaking: the whitening effect of hydrogen peroxide in toothpaste."

The pre-emption argument does not work because Colgate did not identify any federal requirements application to its Optic White products beyond the FDA's general prohibition against false and misleading claims, the judge said.

Other OTC drug firms, like Rx product manufacturers, have made pre-emption arguments against class action claims. Most recently, **Johnson & Johnson** petitioned the Supreme Court to review a $140m judgment for damages in a suit alleging the firm failed to warn that *Children's Motrin* was linked to toxic epidermal necrolysis and Stevens-Johnson syndrome. *(Also see "J&J Petitions Supreme Court On Pre-emption, 'Clear Evidence' In OTC Litigation" - Pink Sheet, 30 Nov, 2015.)*

J&J's pre-emption argument was rejected by lower courts before the Supreme Court declined to consider its appeal. *(Also see "Supreme Court Rejects Most Pharma Cases This Term, But Patent Settlements Stir Interest" - Pink Sheet, 6 Jun, 2016.)*

RB Says Petya Cyberattack Froze Shipments, Could Cost £100M

EILEEN FRANCIS eileen.francis@informa.com

Reckitt-Benckiser Group PLC, among organizations in more than 60 countries that were impacted by the June 27 Petya cyberattack, is projecting around £100m in lost revenues for fiscal 2017.

In a July 6 update, the UK-based firm expresses confidence that damage to its applications and systems has been "materially contained." However, "the attack did disrupt the company's ability to manufacture and distribute products to customers in multiple markets across the RB Group," it says.

"Consequently, we were unable to ship and invoice some orders to customers prior to the close of the quarter. Some of the factories are currently still not operating normally, but plans are in place to return to full operation," according to the release.

The global marketer of *Mucinex* expectorants, *Nurofen* analgesics, *Strepsils* throat lozenges and *Enfamil* infant nutrition, as well as *Clearasil* acne treatments and *Veet* depilatories, now expects organic revenue growth of 2% for the full year, down from the 3% previously forecasted.

Based on the firm's fiscal 2016 net sales of £9.89bn ($12.7bn), the cyberattack's cost to RB's business could be in the neighborhood of £100m ($129m).

RB notes that its adjusted guidance also reflects to some degree reduced product orders in India due to a new goods and services tax.

The Petya-variety malware also infected the systems of pharma giant **Merck & Co.**, which tweeted June 27 that its computer network was "compromised as part of a global hack," but provided no further details.

Germany-based **Beiersdorf AG**, which markets the *Nivea* and *Eucerin* skin-care lines, was affected as well. In a July 3 statement, the company said its email and telephone system had been reactivated at most affiliates and no data had leaked as a result of the attack.

"We are well on track to bring our business operations – including production – fully back to normal to provide our consumers and customers worldwide with the service they are used to," it said.

The widely felt attack, which struck government agencies, banks and companies in the Ukraine before sweeping across the globe, used a modified version of malware similar to that seen in May's WannaCry hack, which locked up National Health Service systems in the UK.

> The threat of cyberattacks on biopharma – which has extensive information assets – has moved up to the top of the list of business risks confronting senior management in that field. Biopharma cyber chiefs had a recent roundtable discussion on the risks of cyberattacks to biopharma company competitiveness and the integrity of relationships with key stakeholders, ranging from key customers and suppliers to patients. *(Also see "Hack Attack: Biopharma Cyber Chiefs Fight Back" - Pink Sheet, 25 Jun, 2017.)*

While such campaigns typically encrypt data and demand ransom payments in Bitcoin currency, the apparent lack of a financial motive in the June attack, among other details, has many security experts suspecting that a nation state, rather than a criminal organization, is to blame.

Russia has been floated as a possible culprit.

ROUGH FEW MONTHS FOR RB

The cyberattack is ill-timed for RB, whose fiscal 2017 first quarter, reported in April, marked its weakest showing in 15 years.

RB attributed its flat sales performance to a consumer backlash in South Korea and a Scholl rechargeable foot file that flopped.

But the firm seems to have turned a corner in its recovery from the virus, certainly in comparison to where it was in its earliest communications to customers.

On the day of the attack, RB's outlook was considerably bleaker. "The virus is highly potent – it's being investigated by government agencies and the major security and technology firms, and there remains only a limited understanding of it and one firm recommendation on how to cope with it," the firm stated.

The company has since underscored that the attack did not impact systems of its newly acquired Mead JohnsonNutrition Co. business. The $17.9bn deal, which closed less than two weeks before the Petya malware reared its head, added Mead's Enfamil brand to RB's lineup and provided it with a platform to expand sales of its existing health, personal and home care products in China. (Also see "Reckitt Expands 'OTC' Business, China Presence With Mead Johnson" - Rose Sheet, 13 Feb, 2017.) *(Also see "Reckitt Expands 'OTC' Business, China Presence With Mead Johnson" - Pink Sheet, 13 Feb, 2017.)*

ANALYSTS WEIGH IN

Analysts are of the opinion that even without the cyberattack, RB was unlikely to have achieved its previous target of 3% organic revenue growth for the year.

"The 3% guidance for 2017 organic growth was already looking [like] a stretch (we had +2.3%), but in light of the recent cyberattack we think it prudent to lower our estimate to +1.6%," says Credit Suisse Analyst Charlie Mills in a July 6 report.

Societe Generale's Jamie Norman, director of the firm's consumer specialist sales unit, offers a similar take on the firm's situation in a same-day analyst report.

"Clearly there will be some questions around whether there are wider problems with RB's model," Norman says. "We continue to see RB as structurally well-placed, as it operates in high-growth, high-gross margin categories and has a gifted and highly incentivized management team. Nevertheless, the market will likely remain skeptical until trading improves."