FEDERAL COMMUNICATIONS COMMISSION

Public Information Collection Requirement Submitted to OMB for Review and Approval, Comments Requested

October 10, 2007.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden, invites the general public and other Federal agencies to take this opportunity to comment on the following information collection, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before November 15, 2007. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, Office of Management and Budget, via Internet at *Nicholas_A._Fraser@omb.eop.gov* or via fax at (202) 395–5167 and to Cathy Williams, Federal Communications Commission, Room 1–C823, 445 12th Street, SW., Washington, DC or via Internet at *Cathy.Williams@fcc.gov* or *pra@fcc.gov.*

To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the web page *http://www.reginfo.gov/public/do/PRAMain,* (2) look for the section of the web page called ''Currently Under Review,'' (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, (6) when the list of FCC ICRs currently under review appears, look for the title of this ICR (or its OMB control number, if there is one) and then click on the ICR Reference Number to view detailed information about this ICR.''

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection(s), contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–1078.

Title: Rules and Regulations Implementing the Controlling the Assault of Non-Solicited Pornography and Marketing Act of 2003, CG Docket No. 04–53.

Form Number: Not applicable.

Type of Review: Extension of a currently approved collection.

Respondents: Individuals or households; business or other for-profit entities; not-for-profit institutions.

Number of Respondents: 5,443,287.

Estimated Time per Response: 1–10 hours (average per response).

Frequency of Response: Recordkeeping requirement; On occasion reporting requirements; third party disclosure requirement.

Obligation To Respond: Required to obtain or retain benefits.

Total Annual Burden: 30,254,598 hours.

Total Annual Cost: $13,639,892.

Nature and Extent of Confidentiality: Confidentiality is an issue to the extent that individuals and households provide personally identifiable information, which is covered under the FCC's system of records notice (SORN), FCC/CGB–1, ''Informal Complaints and Inquiries.''

Privacy Act Impact Assessment: Yes. The Privacy Impact Assessment was completed on June 28, 2007. It may be reviewed at: *http://www.fcc.gov/omd/privacyact/Privacy_Impact_Assessment.html.*

Needs and Uses: The reporting requirements included under this OMB Control Number 3060–1078 enables the Commission to collect information regarding violations of the Controlling the Assault of Non-Solicited Pornography and Marketing Act of 2003 (CAN–SPAM Act). This information is used to help wireless subscribers stop receiving unwanted commercial mobile services messages.

On August 12, 2004, the Commission released an *Order*, Rules and Regulations Implementing the Controlling the Assault of Non-Solicited Pornography and Marketing Act of 2003, CG Docket No. 04–53, FCC 04–194, adopting rules to prohibit the sending of commercial messages to any address referencing an Internet domain name associated with wireless subscribers' messaging services, unless the individual addressee has given the sender express prior authorization.

The information collection requirements consist of 47 CFR 64.3100 (a)(4), (d), (e) and (f) of the Commission's rules.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. E7–20341 Filed 10–15–07; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL TRADE COMMISSION

[File No. 071 0101]

Kyphon Inc., Disc-O-Tech Medical Technologies Ltd. (Under Voluntary Liquidation), and Discotech Orthopedic Technologies Inc.; Analysis of Agreement Containing Consent Orders to Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed Consent Agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices or unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before November 8, 2007.

ADDRESSES: Interested parties are invited to submit written comments. Comments should refer to ''Kyphon Inc., File No. 071 0101,'' to facilitate the organization of comments. A comment filed in paper form should include this reference both in the text and on the envelope, and should be mailed or delivered to the following address: Federal Trade Commission/Office of the Secretary, Room 135-H, 600 Pennsylvania Avenue, NW., Washington, DC 20580. Comments containing confidential material must be filed in paper form, must be clearly labeled ''Confidential,'' and must comply with Commission Rule 4.9(c).

16 CFR 4.9(c) (2005).[1] The FTC is requesting that any comment filed in paper form be sent by courier or overnight service, if possible, because U.S. postal mail in the Washington area and at the Commission is subject to delay due to heightened security precautions. Comments that do not contain any nonpublic information may instead be filed in electronic form as part of or as an attachment to e-mail messages directed to the following e-mail box: *consentagreement@ftc.gov*.

The FTC Act and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. All timely and responsive public comments, whether filed in paper or electronic form, will be considered by the Commission, and will be available to the public on the FTC Web site, to the extent practicable, at*http;//www.ftc.gov*. As a matter of discretion, the FTC makes every effort to remove home contact information for individuals from the public comments it receives before placing those comments on the FTC Web site. More information, including routine uses permitted by the Privacy Act, may be found in the FTC's privacy policy, at*http://www.ftc.gov/ftc/privacy.htm*.

FOR FURTHER INFORMATION CONTACT: Jonathan S. Klarfeld (202) 326-3187, Bureau of Competition, Room NJ-5108, 600 Pennsylvania Avenue, NW., Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46(f), and § 2.34 of the Commission Rules of Practice, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for October 9, 2007), on the World Wide Web, at *http://www.ftc.gov/os/2007/10/index.htm*. A paper copy can be obtained from the FTC Public Reference Room, Room 130-H, 600 Pennsylvania Avenue, NW., Washington, DC 20580, either in person or by calling (202) 326-2222.

Public comments are invited, and may be filed with the Commission in either paper or electronic form. All comments should be filed as prescribed in the **ADDRESSES** section above, and must be received on or before the date specified in the **DATES** section.

Analysis of Agreement Containing Consent Order to Aid Public Comment

I. Introduction

The Federal Trade Commission (''Commission'') has accepted, subject to final approval, an Agreement Containing Consent Orders (''Consent Agreement'') from Kyphon Inc. (''Kyphon'') and Disc-O-Tech Medical Technologies Ltd. (Under Voluntary Liquidation) and Discotech Orthopedic Technologies Inc. (collectively ''Disc-O-Tech''). The purpose of the proposed Consent Agreement is to remedy the anticompetitive effects that would otherwise result from Kyphon's acquisition of Disc-O-Tech's Confidence assets. Under the terms of the proposed Consent Agreement, Kyphon and Disc-O-Tech are required to divest all assets (including intellectual property) related to Disc-O-Tech's Confidence business to a third party, enabling that third party to manufacture and sell the Confidence cement and delivery system for the treatment of vertebral compression fractures.

The proposed Consent Agreement has been placed on the public record for thirty days to solicit comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again review the proposed Consent Agreement and the comments received, and will decide whether it should withdraw the proposed Consent Agreement or make it final.

On December 20, 2006, Kyphon agreed to acquire certain spine-related assets from Disc-O-Tech, including the intellectual property, sales agreements, and other assets relating to Disc-O-Tech's B-Twin, SKy Bone Expander, and Confidence product lines for approximately $220 million (the ''Acquisition''). The Commission's complaint alleges that the proposed acquisition of the assets related to the Confidence system, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, by removing an actual, direct, and substantial competitor from the U.S. market for minimally invasive vertebral compression fracture (''MIVCF'') treatment products. The proposed Consent Agreement would remedy the alleged violation by requiring a divestiture that will replace the competition that otherwise would be lost in this market as a result of the Acquisition.

II. The Parties

Kyphon develops and markets medical devices used to restore and preserve spinal function and diagnose the source of low back pain, including products used to treat vertebral compression fractures in a minimally invasive manner. In 2006, Kyphon reported worldwide sales of approximately $408 million, and U.S. sales of $324 million.

Disc-O-Tech, an Israeli corporation and its U.S. subsidiary that develops, manufactures, and sells products for minimally invasive orthopedic surgeries, introduced the Confidence system to the U.S. market in July 2006. Disc-O-Tech's global revenues were approximately $14 million in 2006.

III. Minimally Invasive Vertebral Compression Fracture Treatments

Vertebral compression fractures (''VCFs'') occur when one or more vertebral bodies collapse. Osteoporosis, a degenerative bone disease that largely affects elderly women, causes the vast majority of VCFs, but they can also be caused by cancerous tumors or traumatic injury. For some patients, VCFs cause extreme, persistent, and debilitating pain.

Doctors and their patients have few ways to effectively treat VCFs. In the past, physicians most commonly treated VCF patients with a variety of pain management techniques such as back braces, bed rest, and pain medication. For many patients, these techniques do not control the pain associated with VCFs and could lead to later health problems. Open surgery involving the placement of metal hardware is rarely performed to repair a VCF because the patients are typically elderly and not good candidates for successful procedures. MIVCF treatments were developed to provide doctors and their patients with a VCF treatment that is more effective than pain management and safer and more effective than open surgery.

Vertebroplasty, the first MIVCF treatment to be introduced, involves the injection of a fairly liquid polymethylmethacrylate bone cement into the fractured vertebral body under fluoroscopy image guidance. The bone

[1] The comment must be accompanied by an explicit request for confidential treatment, including the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. The request will be granted or denied by the Commission's General Counsel, consistent with applicable law and the public interest. *See* Commission Rule 4.9(c), 16 CFR 4.9(c).

cement sets quickly, stabilizing the fracture and eliminating painful movement of loose bone in the vertebra. Vertebroplasty effectively relieves pain, but many doctors have safety concerns regarding the risk of the liquid bone cement leaking out of the vertebral body.

Kyphoplasty, introduced by Kyphon in 1999, is similar to vertebroplasty, except that the physician performs the additional step of inflating one or two balloons inside the vertebral body before injecting the bone cement. The principal advantage of kyphoplasty is that the inflation of the balloons creates a cavity into which the bone cement can flow, reducing the likelihood that cement will leak outside of the vertebral body. Kyphoplasty may have the additional benefit of helping to restore the vertebral body towards its pre-fracture shape and height. Because of its safety advantage and other perceived advantages, kyphoplasty is the most widely used MIVCF treatment product in the United States.

Because of the superiority of MIVCF treatment products over alternatives, the relevant product market in which to analyze the competitive effects of the Acquisition is no larger than MIVCF treatment products. The relevant geographic market is the United States. MIVCF treatment products are medical devices that are regulated by the United States Food and Drug Administration (''FDA''). MIVCF treatment products sold outside the United States, but not approved for sale in the United States, are not viable alternatives for U.S. consumers and hence are not in the relevant market.

Kyphon's premium-priced kyphoplasty product dominates the MIVCF treatment product market with more than a ninety percent share based on revenues. Disc-O-Tech's Confidence system is the first MIVCF treatment product that uses a highly viscous cement. Both Kyphon's product, which uses balloons, and Disc-O-Tech's product, which uses a highly viscous cement, have substantially lower risks of leakage from the vertebral body following injection than do the ''traditional'' vertebroplasty products offered by numerous other firms. All of the latter inject a low viscosity cement. As a result, Disc-O-Tech's Confidence system is poised to become a closer substitute for Kyphon's product than are the traditional vertebroplasty products. For this reason, traditional vertebroplasty products will not constrain the prices for Kyphon's product to the same extent that Disc-O-Tech's Confidence system would, absent its acquisition by Kyphon.

There are other competitors in the MIVCF treatment product market, including Medtronic and Spineology, but none provides the near-term competitive threat to Kyphon posed by Disc-O-Tech's offering. Medtronic has had limited success selling its Arcuate XP product to date, and its product appears to hold limited growth prospects. Spineology's MIVCF offering has been and appears likely to remain a niche product that competes primarily for younger VCF patients. Although several additional firms are attempting to enter the MIVCF treatment product market, the time line for commercialization of these products is significantly behind that of the Confidence system, and none appears to have the Confidence system's immediate prospects for success.

IV. Competitive Effects and Entry Conditions

The Acquisition would cause significant competitive harm in the market for MIVCF treatment products. Confidence is Kyphon's principal competitive threat, and, but for the Acquisition, would make significant inroads into Kyphon's near-monopoly position. Because both products offer a safe method for treating VCFs, many physicians consider the Confidence system to be the best alternative to kyphoplasty, particularly for elderly osteoporotic patients who receive the vast majority of kyphoplasty treatments. By eliminating such a close competitor, the Acquisition would likely allow Kyphon to unilaterally raise prices in the MIVCF treatment market. The anticompetitive effects of the Acquisition are exacerbated by the fact that it appears to have been undertaken with the specific goal of precluding other major spine companies from acquiring Confidence and marketing it against kyphoplasty, which would have happened had Kyphon not acquired Confidence itself. By enabling Kyphon, rather than a major spine company, to control the further development and positioning of Confidence, Kyphon would be able to avoid the competition that it otherwise would have faced in the MIVCF treatment product market. As such, the Acquisition, if consummated, would have a significant, adverse effect on competition.

New entry is not likely to avert the anticompetitive effects of the proposed transaction. It likely would take more than two years for a would-be entrant to develop a product, conduct clinical trials, and submit the product for FDA approval. After submitting an application for FDA clearance or approval, a firm must wait for the FDA to review the material and respond to any questions the FDA may have. In addition to the development and regulatory time requirements for firms seeking to enter the MIVCF treatment product market, there are substantial intellectual property barriers an entrant must overcome. Patent litigation among competitors in this market is ongoing, and key patents act as a major obstacle to any prospective entrant. As such, any new MIVCF treatment device of any competitive significance would have to be designed around existing patents. Finally, even after a non-infringing design is developed and the product is manufactured, a firm would still need to establish a U.S. sales and marketing force. Considering all these factors, entry into the manufacture and sale of MIVCF treatment products is likely to take longer than two years. Thus, timely and sufficient entry in response to a small but significant price increase is extremely unlikely.

V. The Proposed Consent Agreement

The parties have agreed, pursuant to the proposed Consent Agreement, to divest Disc-O-Tech's Confidence assets to a Commission-approved acquirer no later than 60 days after the Commission accepts the Consent Agreement for public comment, effectively remedying the Acquisition's anticompetitive effects in the MIVCF treatment product market. The Consent Agreement requires that the parties divest all assets relating to the Confidence system, including tangible property, intellectual property, and any permits and licenses that are necessary to manufacture, distribute, and sell the Confidence system. In addition, the parties must divest the rights to certain Disc-O-Tech development efforts related to the Confidence system. To the extent that an acquirer of the Confidence assets requires additional assets not included in the asset package, the Consent Agreement requires Kyphon to provide a license to any other assets it acquired from Disc-O-Tech, which will ensure that the acquirer will be able to immediately enter the MIVCF treatment product market and remain a viable competitor.

The proposed Consent Agreement contains several provisions to help ensure that the divestiture is successful. First, the Commission will evaluate possible purchasers of the divested assets to ensure that the competitive environment that would have existed but for the transaction is restored. If the parties do not divest the Confidence assets within the 60-day time period to a Commission-approved buyer, or if Kyphon closes on the acquisition of the

Confidence assets, the Consent Agreement provides for the Commission to appoint a trustee to divest the assets. Second, Disc-O-Tech is required to provide transitional services to the Commission-approved buyer. These transitional services, which are similar in form to what Disc-O-Tech would have provided to Kyphon, may be necessary for a smooth transition of the Confidence assets to the acquirer and to ensure continued and uninterrupted service to customers during the transition. The Consent Agreement also requires that Kyphon covenant not to sue the acquirer of the Confidence assets for infringing any intellectual property Kyphon acquired from Disc-O-Tech that is not being divested. This covenant covers not only the Confidence assets, but also extends to any developments an acquirer might make to the Confidence assets. This provision is designed as a safety net to ensure that Kyphon does not interfere with the acquirer's freedom to compete in the U.S. MIVCF treatment product market with a patent infringement lawsuit based on former Disc-O-Tech intellectual property. Finally, to ensure that the Commission will have an opportunity to review any attempt by Kyphon to acquire or license any of the Confidence assets at any time within the next two years, the proposed Consent Agreement contains a prior notice provision committing Kyphon to an H-S-R framework, even if such a transaction otherwise would be non-reportable.

The Order to Hold Separate and Maintain Assets that is included in the Consent Agreement requires that Disc-O-Tech maintain the viability of the Confidence business as a competitive operation until the business is transferred to a Commission-approved buyer. Specifically, Disc-O-Tech must maintain the confidentiality of sensitive business information, and take all actions required to prevent the destruction or wasting of the Confidence assets. Kyphon may not interfere with the Confidence business during the pendency of the divestiture by having any involvement in the Confidence business, making offers of employment to Disc-O-Tech employees involved in the Confidence business before the Confidence assets are divested, or interfering with Disc-O-Tech's suppliers of materials for the Confidence product.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Decision and Order or to modify its terms in any way.

By direction of the Commission, with Commissioners Harbour and Kovacic recused.

Donald S. Clark,

Secretary.

[FR Doc. E7–20325 Filed 10–15–07: 8:45 am]

[Billing Code: 6750–01–S]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Training Program for Regulatory Project Managers; Information Available to Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) is announcing the continuation of the Regulatory Project Management Site Tours and Regulatory Interaction Program (the Site Tours Program). The purpose of this document is to invite pharmaceutical companies interested in participating in this program to contact CDER.

DATES: Pharmaceutical companies may submit proposed agendas to the agency by December 17, 2007.

ADDRESSES: Submit written proposed agendas regarding the Site Tours Program to Beth Duvall-Miller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6466, Silver Spring, MD 20993–0002. You can also reach Beth Duvall-Miller by telephone at 301–796–0700 or by e-mail at *elizabeth.duvallmiller@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

An important part of CDER's commitment to make safe and effective drugs available to all Americans is optimizing the efficiency and quality of the drug review process. To support this primary goal, CDER has initiated various training and development programs to promote high performance in its regulatory project management staff. CDER seeks to enhance significantly review efficiency and review quality by providing the staff with a better understanding of the pharmaceutical industry and its operations. To this end, CDER is continuing its training program to give regulatory project managers the opportunity to tour pharmaceutical facilities. The goals are to provide the following: (1) Firsthand exposure to industry's drug development processes and (2) a venue for sharing information about project management procedures (but not drug-specific information) with industry representatives.

II. The Site Tours Program

In this program, over a 2- to 3-day period, small groups (five or less) of regulatory project managers, including a senior level regulatory project manager, can observe operations of pharmaceutical manufacturing and/or packaging facilities, pathology/toxicology laboratories, and regulatory affairs operations. Neither this tour nor any part of the program is intended as a mechanism to inspect, assess, judge, or perform a regulatory function, but is meant rather to improve mutual understanding and to provide an avenue for open dialogue. During the Site Tours Program, regulatory project managers will also participate in daily workshops with their industry counterparts, focusing on selective regulatory issues important to both CDER staff and industry. The primary objective of the daily workshops is to learn about the team approach to drug development, including drug discovery, preclinical evaluation, tracking mechanisms, and regulatory submission operations. The overall benefit to regulatory project managers will be exposure to project management, team techniques, and processes employed by the pharmaceutical industry. By participating in this program, the regulatory project manager will grow professionally by gaining a better understanding of industry processes and procedures.

III. Site Selection

All travel expenses associated with the site tours will be the responsibility of CDER; therefore, selection will be based on the availability of funds and resources for each fiscal year. Firms interested in offering a site tour or learning more about this training opportunity should respond by (see **DATES**) by submitting a proposed agenda to Beth Duvall-Miller (see **ADDRESSES**).

Dated: October 9, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–20430 Filed 10–15–07; 8:45 am]

BILLING CODE 4160–01–S