The following types of interventions are not eligible for review and should not be submitted to NREPP:

1. Stand-alone pharmacologic treatments—The evidence base for pharmacologic treatments is reviewed and approved through the U.S. Food and Drug Administration (FDA). FDA-approved pharmacotherapy interventions (on-label use) are considered for NREPP review only when combined with one or more behavioral or psychosocial treatments.

2. Stand-alone smoking prevention and/or cessation interventions—Interventions to prevent or reduce tobacco use are eligible for NREPP review only when conducted as part of a program that also addresses the prevention or treatment of alcohol or other drugs of abuse.

3. To remain consistent with SAMHSA's mission ("to reduce the impact of substance abuse and mental illness on American communities"), NREPP will not accept for review, or otherwise include on the NREPP Web site, any interventions that have been developed or evaluated with funds or other support-either partially or wholly-from organizations whose goals or activities are determined to be inconsistent with SAMHSA's mission.

4. Due to a combination of limited resources and a large number of previously accepted mental health submissions, only a small number of mental health promotion or mental health treatment interventions will be accepted for review by NREPP in FY 2011.

5. Because of limited resources for FY 2011, multiple submissions from the same developer-regardless of content area-will not be accepted.

Selection of Interventions for Review

All submissions meeting the minimum requirements will be considered eligible for review. In selecting interventions for review, SAMHSA may choose to give special consideration to interventions that meet one or more of the following conditions:

- The original investigator(s) or an independent party has used the same protocol with an identical or similar target population, and/or has used a slightly modified protocol based on a slightly modified population, where results are consistent with positive findings from the original evaluation.
- Implementation materials (*e.g.,* program manuals, training guides, measurement instruments, implementation fidelity guides) are available to the public at no cost.
- The intervention targets underserved populations (*e.g.,* minority populations, elderly, young adults, individuals who are incarcerated).
- The intervention contributes to a content area where there are currently limited evidence-based interventions.

Interventions that are not selected for review may be resubmitted by the applicant in a future open submission period.

Instructions for Submitting an Intervention

To submit an intervention, individuals should send a written statement to NREPP expressing their interest along with documentation that demonstrates the intervention meets the minimum requirements as described above. All submissions must be made either by a principal investigator (PI) who has conducted research on the intervention, a a project director (PD) who has worked with an evaluator of the intervention, or a formally authorized delegate of the PI or PD. For information on where to submit materials, please call 1–866–436–7377. Electronic submissions are preferred, but materials may be sent to NREPP in hard copy via postal mail or fax. To be eligible for consideration, submissions must be received no later than 11:59 p.m. EST on February 1, 2011; those received before November 1, 2010, will be disregarded.

If an intervention is accepted, the PI will be contacted and asked to submit additional documentation to be used in the review. This additional documentation includes full-text copies of all articles and reports that provide evidence of significant outcomes (p ~05) as well as copies of selected dissemination materials in the format they are provided to the public (*e.g.,* hard copies or electronic versions of manuals, training presentations, tools, quality assurance protocols; URLs for interactive Web-based resources).

The PI is expected to serve as the main point of contact throughout the remainder of the review process, including approval of the final intervention summary that is developed by NREPP staff once the review has been completed.

Contact Information

Individuals who have questions about the information contained in this notice may write to NREPP staff at *nrepp@samhsa.hhs.gov* or call 1–866–436–7377.

[FR Doc. 2010–20016 Filed 8–17–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0422]

Agency Information Collection Activities; Proposed Collection; Comment Request; Information From United States Processors That Export to the European Community

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting requirements in implementing the lists of U.S. firms/processors exporting shell eggs, dairy products, game meat, game meat products, animal casings, gelatin, and collagen to the European Community (the EC).

DATES: Submit either electronic or written comments on the collection of information by October 18, 2010.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide

information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Information From U.S. Processors That Export to the European Community (OMB Control Number 0910–0320)—Extension

The EC is a group of 27 European countries that have agreed to harmonize their commodity requirements to facilitate commerce among member States. EC legislation for intra-EC trade has been extended to trade with non-EC countries, including the United States. For certain food products, including those listed in this document, EC legislation requires assurances from the responsible authority of the country of origin that the processor of the food is in compliance with applicable regulatory requirements.

FDA requests information from processors that export certain animal-derived products (e.g., shell eggs, dairy products, game meat, game meat products, animal casings, and gelatin) to the EC. FDA uses the information to maintain lists of processors that have demonstrated current compliance with U.S. requirements and provides the lists to the EC quarterly. Inclusion on the list is voluntary. EC member countries refer to the lists at ports of entry to verify that products offered for importation to the EC from the United States are from processors that meet U.S. regulatory requirements. Products processed by firms not on the lists are subject to detention and possible refusal at the port. FDA requests the following information from each processor seeking to be included on the lists:

- Business name and address;
- Name and telephone number of person designated as business contact;
- Lists of products presently being shipped to the EC and those intended to be shipped in the next 6 months;
- Name and address of manufacturing plants for each product; and
- Names and affiliations of any Federal, State, or local governmental agencies that inspect the plant, government-assigned plant identifier such as plant number, and last date of inspection.

Description of Respondents: The respondents to this collection of information include U.S. producers of shell eggs, dairy products, game meat, game meat products, animal casings, gelatin, and collagen.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Products	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Shell Eggs	10	1	10	0.25	3
Dairy	120	1	120	0.25	30
Game Meat and Game Meat Products	5	1	5	0.25	1
Animal Casings	5	1	5	0.25	1
Gelatin	3	1	3	0.25	1
Collagen	3	1	3	0.25	1
Total					37

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA bases its estimates of the number of respondents and total annual responses on the submissions that the agency has received in the past 3 years for each product type. To calculate the estimate for the hours per response values, we assumed that the information requested is readily available to the submitter. We expect that submitter will need to gather information from appropriate persons in the submitter's company and to prepare this information for submission. We believe that this effort should take no longer than 15 minutes (0.25 hour) per response. FDA estimates that it will receive 1 submission from 10 shell egg producers annually, for a total of 10 annual responses. Each submission is estimated to take 0.25 hour per response for a total of 2.5 hours, rounded to 3 hours. FDA estimates that it will receive 1 submission from 120 dairy product producers annually, for a total of 120 annual responses. Each submission is estimated to take 0.25 hour per response for a total of 30 hours. FDA estimates that it will receive 1 submission from 5 game meat and game meat product producers annually, for a total of 5 annual responses. Each submission is estimated to take 0.25 hour per response for a total of 1.25 hours, rounded to 1 hour. FDA estimates that it will receive 1 submission from 5 animal casings producers annually, for a total of 5 annual responses. Each submission is estimated to take 0.25 hour per response for a total of 1.25 hours, rounded to 1 hour. FDA estimates that it will receive 1 submission from 3 gelatin producers annually, for a total of 3 annual responses. Each submission is estimated to take 0.25 hour per response for a total of 0.75 hour, rounded to 1 hour. FDA estimates that it will receive 1 submission from 3 collagen producers annually, for a total of 3 annual

responses. Each submission is estimated to take 0.25 hour per response for a total of 0.75 hour, rounded to 1 hour.

Therefore, the proposed annual burden for this information collection is 37 hours.

Dated: August 12, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–20379 Filed 8–17–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0139]

Seth M. Yoser: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) (the Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the act) permanently debarring Seth M. Yoser, MD from providing services in any capacity to a person that has an approved or pending drug product application. We base this order on a finding that Dr. Yoser was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act. Dr. Yoser was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. In a May 20, 2010, letter to FDA, Dr. Yoser, through counsel, notified FDA that he acquiesces to debarment and therefore he has waived his right to a hearing concerning this action.

DATES: This order is effective May 20, 2010.

ADDRESSES: Submit applications for special termination of debarment to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kenny Shade, Division of Compliance Policy (HFC–230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–632–6844.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(B) of the act (21 U.S.C. 335a(a)(2)(B)) requires debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct otherwise relating to the regulation of any drug product under the act.

On February 23, 2010, the U.S. District Court for the Western District of Tennessee entered judgment against Dr. Yoser for ten counts of mail fraud in violation of 21 U.S.C. 1341, twenty-three counts of unlicensed wholesale distribution of prescription drugs in violation of 21 U.S.C. 331(t), 333(b)(1)(D), and 353(e)(2)(A); and two counts of wire fraud in violation of 18 U.S.C. 1343.

FDA's finding that debarment is appropriate is based on the felony convictions referenced herein for conduct relating to the regulation of a drug product. The factual basis for those convictions is as follows: Dr. Yoser was employed by the Eye Specialty Group (ESG), formerly known as the Vitreorentinal Foundation, and he was a partner of ESG from on or about June 2005, until approximately May 12, 2008. During the course of his employment and partnership with ESG, he performed treatments which included administering the prescription drugs Visudyne, Lucentis, and Avastin to treat Wet Aged Macular Degeneration.

Beginning on or about July 1, 2002, and continuing up to and including May 12, 2008, Dr. Yoser did knowingly devise a scheme and artifice to defraud ESG and Medicare in order to obtain money and property by means of false and fraudulent representation, billing, and pretense. As part of that scheme, he billed Medicare for Visudyne, Avastin, and Lucentis that he purportedly used to treat ESG patients but that he actually diverted from ESG patients and sold.

Beginning on or about April 14, 2004, through on or about October 2, 2007, in the Western District of Tennessee, and elsewhere, Dr. Yoser did knowingly engage in or cause the wholesale distribution in interstate commerce of the prescription drugs, Visudyne and Lucentis in Louisiana, Tennessee, Texas, and Arkansas without being licensed by those states in violation of 21 U.S.C. 331(t), 333(b)(1)(D), and 353(e)(2)(A).

As a result of his convictions, on April 19, 2010, FDA sent Dr. Yoser a notice by certified mail proposing to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(B) of the act, that Dr. Yoser was convicted of felonies under Federal law for conduct relating to the regulation of a drug product under the act. The proposal also offered Dr. Yoser an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Dr. Yoser's attorney filed a May 20, 2010, response in which he stated that Dr. Yoser did not object to debarment and further clarified in writing that the May 20, 2010, letter intended to express Dr. Yoser's acquiescence to debarment. By acquiescing to debarment, as provided for in section 306(c)(2)(B) of the act, Dr. Yoser waived his opportunity for a hearing and any contentions concerning his debarment.

II. Findings and Order

Therefore, the Director, Office of Enforcement, Office of Regulatory Affairs, under section 306(a)(2)(B) of the act, under authority delegated to the Acting Director (Staff Manual Guide 1410.35), finds that Seth M. Yoser has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act.

As a result of the foregoing finding and based on his notification of acquiescence, Dr. Yoser is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective May 20, 2010, the date of the notification of acquiesce (see **DATES**) (see sections 306(c)(1)(B), (c)(2)(A)(ii), (c)(2)(B), and 201(dd) of the act (21 U.S.C. 335a(c)(1)(B), (c)(2)(A)(ii), (c)(2)(B), and 321(dd))). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Dr. Yoser, in any capacity during Dr. Yoser's debarment, will be subject to civil money penalties (section 307(a)(6) of the act (21 U.S.C. 335b(a)(6))). If Dr. Yoser provides services in any capacity to a person with an approved or pending drug product application during his period of debarment he will be subject to civil money penalties (section 307(a)(7) of the act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Dr. Yoser during his period of debarment (section 306(c)(1)(B) of the act).

Any application by Dr. Yoser for special termination of debarment under section 306(d)(4) of the act should be