

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Job Search Assistance (JSA) Strategies Evaluation.

OMB No.: 0970-0440.

Description: The Administration for Children and Families (ACF) is proposing a data collection activity as part of the Job Search Assistance (JSA) Strategies Evaluation. The JSA evaluation will aim to determine which JSA strategies are most effective in

moving TANF applicants and recipients into work. The impact study will randomly assign individuals to contrasting JSA approaches and then compare their employment and earnings to determine their relative effectiveness. The implementation study will describe services participants receive under each approach as well as provide operational lessons gathered directly from practitioners.

The proposed information collection activity consists of: (1) Baseline data collection: Collection of baseline data from TANF recipients at the time of enrollment in the study; (2) Implementation study site visits: Conducting site visits for the purpose of

documenting the program context, program organization and staffing, the components JSA services, and other relevant aspects of the TANF program. During the visits, site teams will interview key administrators and line staff using a semi-structured interview guide; and (3) a JSA staff survey. This on-line survey, administered to TANF supervisory and line staff involved in JSA activities, will be used as part of the implementation study to systematically document program operations and the type of JSA services provided across the study sites.

Respondents: JSA program staff and individuals enrolled in the JSA study.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
Baseline information form	25,000	1	0.2	5,000
Implementation study site visits	300	1	1	300
JSA staff survey	660	1	0.33	218
Estimated Total Annual Burden Hours				5,518

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. Email address: OPREinfocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to

comments and suggestions submitted within 60 days of this publication.

Karl Koerper,
Reports Clearance Officer.
 [FR Doc. 2014-13525 Filed 6-10-14; 8:45 am]
BILLING CODE 4184-09-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0595]

Environmental Protection Agency and Food and Drug Administration Advice About Eating Fish: Availability of Draft Update

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of docket; request for comments.

SUMMARY: In March 2004, the Food and Drug Administration (FDA) and the U.S. Environmental Protection Agency (EPA) (the Agencies) jointly released a document entitled "What You Need to Know About Mercury in Fish and Shellfish" (the 2004 advice). FDA and EPA are now announcing a draft update that contains both advice and supplemental questions and answers for those who want to understand the advice in greater detail. FDA and EPA are establishing a public docket and

seeking public comment on both the substance of the advice and how best to frame the advice for consumers so that it is both understandable and influential. In addition to inviting public comments, the Agencies intend to seek the input of the FDA Advisory Committee on Risk Communication in a meeting open to the public. The Agencies may also hold public meetings in various locations around the country. Information about any such meetings will be published in the **Federal Register** once dates and locations are confirmed.

DATES: The comment period will be open until 30 days after the last transcript from the advisory committee meeting and the other meetings mentioned previously becomes available. The date for closure of public comment will be published in a future notice in the **Federal Register**.

ADDRESSES: Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. FDA will share with EPA all comments submitted to the FDA docket.

FOR FURTHER INFORMATION CONTACT:
 FDA: Philip Spiller, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835,

240–402–1428, email: *Philip.Spiller@fda.hhs.gov*; EPA: Jeffrey Bigler, MS–4305T, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460, 202–566–0389, email: *bigler.jeff@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Fish and shellfish (referred to collectively in this notice as “fish”) provide protein, are low in saturated fat, and are rich in many micronutrients; they also provide certain omega-3 fatty acids (Ref. 1). However, as a result of natural processes and human activity, fish also contain mercury in the form of methylmercury. Methylmercury can adversely affect the central nervous system, particularly the developing brain of the fetus.

FDA issued fish consumption advice relating to mercury in 1994, followed by separate, but simultaneously issued, FDA and EPA fish consumption advice in 2001. FDA’s 2001 advice addressed commercial fish; EPA’s 2001 advice addressed locally caught fish. In March 2004, FDA and EPA jointly issued a document entitled “What You Need to Know About Mercury in Fish and Shellfish; 2004 EPA and FDA Advice for: Women Who Might Become Pregnant, Women Who Are Pregnant, Nursing Mothers, Young Children” (Ref. 2). The 2004 advice was issued to help individuals in the target population limit their exposure to mercury while still obtaining the health benefits of fish consumption. The 2004 advice recommends avoiding four types of commercially available fish that have the highest average mercury concentrations: Tilefish, shark, swordfish, and king mackerel. The advice further recommends that women in the target population eat up to—but not exceed—12 ounces per week of most other types of commercially available fish. It recommends limiting consumption of one species, white (albacore) tuna, to no more than 6 ounces per week. For local fish caught by family and friends, the advice recommends following locally posted fish advisories regarding safe catch. Where no such advice exists, it recommends limiting consumption of locally caught fish to 6 ounces per week and eating no other fish that week.

The 2004 advice is no longer entirely consistent with the most current U.S. Dietary Guidelines for Americans (DGAs), which are issued jointly every 5 years by HHS and USDA. HHS and USDA recommend in the *Dietary Guidelines for Americans 2010* that “women who are pregnant or breastfeeding consume at least 8 and up

to 12 ounces per week of a variety of seafood per week, from choices lower in methyl mercury” taking into account evidence relating fish consumption to improved infant health and developmental outcomes¹ (Refs. 3 and 4). While the 2004 advice encourages fish consumption as part of a healthy diet, it does not encourage consumption of any particular amount of fish in order to improve health and developmental outcomes. As an additional matter, quantitative assessments recently performed have produced results that support the quantitative recommendations in the 2010 DGAs. These assessments estimate risks and benefits to neurodevelopment from fish consumption during pregnancy. They estimate “net effects” from eating fish during pregnancy by estimating both adverse effects from mercury and beneficial effects from nutrients in fish. These assessments include a 2011 report by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) entitled “Report of the Joint FAO/WHO Expert Consultation on the Risks and Benefits of Fish Consumption” (Ref. 5) and a 2014 assessment conducted by FDA entitled, “A Quantitative Assessment of the Net Effects on Fetal Neurodevelopment from Eating Commercial Fish (As Measured by IQ and also by Early Age Verbal Development in Children)” (Ref. 6). The FDA assessment was first published in draft in 2009 and then recently revised to incorporate comments and advice from peer reviewers, the public, and other Federal Agencies, including recent comments from EPA. In addition, since 2004 there have been other publications in the peer reviewed scientific literature evaluating the benefits of fish consumption versus risks of mercury exposure (Refs. 7 and 8).

II. What is being proposed in the draft updated advice?

FDA and EPA are now proposing to update their 2004 advice to make it consistent with the recommendations in the *Dietary Guidelines for Americans 2010*. It is important that advice on fish consumption be harmonized across Federal Agencies. Inconsistent advice can cause confusion and undermine the public health objectives that the advice

¹ A review of the evidence taken into account in the development of the fish consumption recommendation in the *Dietary Guidelines for Americans 2010* can be found on pages 239–241 in the “Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans,” 2010, at <http://www.cnpp.usda.gov/DGAs2010-DGACReport.htm>.

is intended to accomplish. The Agencies are also proposing to modify the wording and organization of the 2004 advice in order to enhance the likelihood that it will be followed by the target audience. Consuming 8 to 12 ounces of fish per week while pregnant or breastfeeding would be a significant dietary change for most women. In a survey of over 1,200 pregnant women conducted by FDA in 2005, median fish consumption was 1.8 ounces per week (Ref. 9).

Consistent with the *Dietary Guidelines for Americans 2010*, the draft updated advice would:

- *Recommend that pregnant women, women who might become pregnant, and breastfeeding mothers eat at least 8 and up to 12 ounces per week of a variety of fish lower in mercury within their calorie needs.* The draft updated advice also describes this amount as 2 or 3 servings per week. The 2004 advice translated 12 ounces into 2 servings based on an assumption that a single serving is likely to be around 6 ounces; however, there is variability surrounding serving sizes and single servings can often be somewhat smaller than 6 ounces (Refs. 10, 11, and 12). The proposed consumption target of 8 to 12 ounces per week of fish lower in mercury is designed to maximize the potential health and developmental benefits that fish could provide. The recommendation to stay within calorie needs is aimed at insuring that women who eat more fish in order to achieve 8 to 12 ounces of fish per week do not inadvertently exceed the number of calories that are appropriate for them when they do so.

- *Continue to recommend that the target audience avoid certain fish with the highest mercury concentrations; those fish are tilefish, shark, swordfish, and king mackerel.* It would recommend avoidance of tilefish only from the Gulf of Mexico, however. Data on tilefish from the Atlantic Ocean indicate that these fish have much lower levels of mercury on average (Ref. 13).

- *Advise members of the target audience that they may eat tuna but continue to recommend limiting white (albacore) tuna to 6 ounces per week.*

- *Retain the recommendations included in the 2004 advice for fish caught in local streams, rivers, and lakes.* There are local waters where there may have been little or no monitoring and, therefore, the extent of potential mercury contamination is unknown. Fish in local waters can contain higher levels of mercury than commercially available species. Local freshwater fish may also differ in their nutritional composition.

• *Continue to extend the recommendations in the 2004 advice to young children because their nervous systems are still developing.* The *Dietary Guidelines for Americans 2010* do not provide specific feeding recommendations for infants and young children under the age of 2 years, but they do note that the nutritional value of fish is of particular importance in early infancy from maternal consumption and in childhood (Ref. 3). The draft updated advice would continue to recommend that the portions for children be smaller than those for adult women and the accompanying questions and answers (Q & A) would provide advice on specific consumption amounts for fish in general and for albacore tuna.

• *Note that fish provides health benefits for the general public.* This information is intended for the general public, not just for the target audience. The *Dietary Guidelines for Americans 2010* recommend that the general public increase the amount and variety of fish consumed.

III. What else are FDA and EPA seeking comment on?

In addition to requesting comments on the substance of the draft updated advice, FDA and EPA are seeking public comment on alternative risk communication approaches for conveying the message and its supplemental Q & A. The Agencies recognize that how the message is conveyed can be highly important to its success. The approach in this draft update seeks to balance simplicity of message with specificity of information. FDA and EPA believe that public input is required to assist in achieving this balance. FDA and EPA anticipate the public process will address how best to provide accurate, balanced descriptions of the purpose for the updated advice and the potential benefits and risks of fish consumption.

FDA and EPA further anticipate that the public process will address whether the questions in the draft supplemental Q & A are appropriate and represent those most likely to be asked by consumers, and whether the answers are accurate and sufficiently informative to encourage more consumption of fish and to guide consumers to fish lower in mercury.

On a specific matter, the Agencies are interested in public comment on whether to add two additional fish to the list of fish that members of the target audience should not eat. Because the draft updated advice tracks the *Dietary Guidelines for Americans 2010*, the draft updated advice recommends

essentially² the same fish to avoid as is recommended in the DGAs. They are: (1) Tilefish from the Gulf of Mexico (average of 1.45 parts per million (ppm) of mercury); (2) swordfish (average of 1.00 ppm of mercury); (3) shark (average of 0.98 ppm of mercury); and (4) king mackerel (average of 0.73 ppm of mercury). The average mercury concentrations in these fish are notably higher than the concentrations in all other commercial species. FDA and EPA are seeking comment on whether to add orange roughy and marlin to the list of fish to avoid. While orange roughy and marlin are lower in mercury than the four fish listed previously (orange roughy averages 0.57 ppm mercury, which equals 80 micrograms/4 ounce (oz.) of cooked fish, and marlin averages 0.49 ppm mercury, which equals 69 micrograms/4 oz. of cooked fish), their mercury concentrations are higher than nearly all other commercial fish. Moreover, both orange roughy and marlin can be unusually low in omega-3 fatty acids. Omega-3 fatty acids may contribute to the healthful effects from fish, although the supporting science is not settled on this point. For those reasons, we particularly invite comment on whether it would be prudent for pregnant women or those who might become pregnant, breastfeeding women, and young children, to avoid orange roughy and marlin in addition to the four other fish to avoid.

FDA and EPA used sampling data from FDA and, to a limited extent, from the U.S. National Marine Fisheries Service as the source for mercury amounts in fish. FDA and EPA used data developed by the USDA to estimate the amounts of the omega-3 fatty acids eicosapentaenoic acid and docosahexanoic acid in fish.

Additionally, the Agencies invite comment on the following:

(1) Whether the final updated advice should track the *Dietary Guidelines for Americans 2010* more or less closely than the draft of that updated advice now does.

(2) Any new science that has become available since the *Dietary Guidelines for Americans 2010* were issued that would be relevant to the updated advice.

(3) Information upon which to base advice on young children's fish consumption. There have been a number of studies that have examined the effects of both postnatal exposure to mercury as well as postnatal fish consumption by young children, but

² As stated previously, our recommendation for tilefish now relates only to tilefish from the Gulf of Mexico and not to Atlantic tilefish.

this research has not been as extensive as the research on prenatal exposures and maternal fish consumption.

(4) As stated previously, suggestions for improving the clarity and utility of the advice.

(5) How to integrate advice from local advisories for those who consume fish from local streams, rivers, and lakes.

IV. How To Submit Comments

Interested persons may submit either electronic comments regarding the draft documents to <http://www.regulations.gov> or written comments regarding the draft documents to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

V. How To Access the Draft Documents

The draft documents described in this notice are available electronically at <http://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/ucm393070.htm> and at <http://water.epa.gov/scitech/swguidance/fishshellfish/fishadvisories/index.cfm>.

VI. References

FDA has placed the following references on display in FDA's Division of Dockets Management (see **ADDRESSES**). You may see them between 9 a.m. and 4 p.m., Monday through Friday, and online at <http://www.regulations.gov>. (FDA has verified all the Web site addresses in this reference section, but FDA is not responsible for any subsequent changes to Web sites after this document publishes in the **Federal Register**.)

1. Institute of Medicine, Committee on Nutrient Relationships in Seafood: "Selections to Balance Benefits and Risks," (2007). *Seafood Choices, Balancing Benefits and Risks*. The National Academies Press, Washington, DC.
2. "What You Need to Know About Mercury in Fish and Shellfish; 2004 EPA and FDA Advice for: Women Who Might Become Pregnant, Women Who are Pregnant, Nursing Mothers, Young Children," available at: <http://www.fda.gov/food/foodborneillnesscontaminants/buytoreservesafe/ucm110591.htm>.
3. U.S. Departments of Agriculture and Health and Human Services, (2010). *Dietary Guidelines for Americans 2010*, chapter 4, "Foods and Nutrients to Increase," available at

<http://health.gov/dietaryguidelines/2010.asp>.

4. "Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans," 2010 to the Secretary of Agriculture and the Secretary of Health and Human Services, available at <http://www.cnpp.usda.gov/DGAs2010-DGACReport.htm>.
5. FAO/WHO, (2011). "Report of the Joint FAO/WHO Expert Consultation on the Risks and Benefits of Fish Consumption," Rome, 25–29 January 2010. FAO Fisheries and Aquaculture Report No. 978 FIPM/R978(En).
6. "A Quantitative Assessment of the Net Effects on Fetal Neurodevelopment From Eating Commercial Fish (As Measured by IQ and also by Early Age Verbal Development in Children)." Available at: <http://www.fda.gov/Food/FoodbornellnessContaminants/Metals/ucm393211.htm>.
7. Cohen, J.T., DC Bellinger, W.E. Connor, et al., (November 2005). "A Quantitative Risk-Benefit Analysis of Changes in Population Fish Consumption," *American Journal of Preventive Medicine*, vol. 29(4), pp. 325–334.
8. Ginsberg, C.L. and B.F. Toal, (2009). Quantitative Approach for Incorporating Methylmercury Risks and Omega-3 Fatty Acid Benefits in Developing Species-Specific Fish Consumption Advice. *Environmental Health Perspectives*, vol. 117(2), pp. 267–275.
9. Lando, A.M., S.B. Fein, and C.J. Choinière, (2012). "Awareness of Methylmercury in Fish and Fish Consumption Among Pregnant and Postpartum and Women of Childbearing Age in the United States," *Environmental Research*, vol. 116, pp. 85–92.
10. Daniels, J.L., M.P. Longnecker, A.S. Rowland, J. Golding, and the ALSPAC Study Team University of Bristol Institute of Child Health, (July 2004). "Fish Intake During Pregnancy and Early Cognitive Development of Offspring," *Epidemiology*, vol. 15(4), pp. 394–402.
11. FAO/WHO, (2011). "Report of the Joint FAO/WHO Expert Consultation on the Risks and Benefits of Fish Consumption," Rome, January 25–29, 2010. FAO Fisheries and Aquaculture Report No. 978 FIPM/R978(En) (see page 26).
12. Institute of Medicine, Committee on Nutrient Relationships in Seafood: "Selections to Balance Benefits and Risks," (2006). *Seafood Choices, Balancing Benefits and Risks*. The National Academies Press, Washington, DC. (see page 240).
13. "Mercury Levels in Commercial Fish and Shellfish 1990–2010," available at: <http://www.fda.gov/Food/FoodbornellnessContaminants/Metals/ucm115644.htm>.

Dated: June 6, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–13584 Filed 6–10–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–E–0713]

Determination of Regulatory Review Period for Purposes of Patent Extension; Vandetanib

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for VANDETANIB and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO) for the extension of a patent which claims that human drug product.

ADDRESSES: Submit electronic comments to <http://www.regulations.gov>. Submit written petitions (two copies are required) and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit petitions electronically to <http://www.regulations.gov> at Docket No. FDA–2013–S–0610.

FOR FURTHER INFORMATION CONTACT:

Beverly Friedman, Office of Management, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6257, Silver Spring, MD 20993–0002, 301–796–7900.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval

phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product Vandetanib. Vandetanib is indicated for the treatment of symptomatic or progressive medullary thyroid cancer in patients with unresectable locally advanced or metastatic disease. Subsequent to this approval, the USPTO received a patent term restoration application for Vandetanib (U.S. Patent No. RE42,353) from AstraZeneca UK Limited, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 9, 2012, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of Vandetanib represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Vandetanib is 4,009 days. Of this time, 3,735 days occurred during the testing phase of the regulatory review period, while 274 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* April 16, 2000. The applicant claims April 20, 2000, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was April 16, 2000, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* July 7, 2010. FDA has verified the applicant's claim that the new drug application (NDA) for Vandetanib (NDA 22–405) was submitted on July 7, 2010.

3. *The date the application was approved:* April 6, 2011. FDA has