3,400 families who include a pregnant woman or a child under 12 months of age, in 17 EHS study sites. Each family will be randomly assigned to a treatment group or a control group. The sample for the child care assessments will include the primary child care provider for the focal child in each of the 3,400 study sample families. The sample for the staff assessments will be all EHS staff who have contact with the study children and families. The surveys and assessments will be conducted through computer assisted telephone interviewing, pencil and paper self-administered questionnaires, structured observations and videotaping. All data collection instruments have been designed to minimize the burden on respondents by minimizing interviewing and assessment time. Participation in the study is voluntary and confidential.

The information will be used by government managers, Congress and others to identify the features and evaluate the effectiveness of the EHS program.

Respondents: Applicants to the Early Head Start program, child care providers for Early Head Start families and Early Head Start staff.

Annual Burden Estimates:

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
14-Month Parent Interview, Child Assessment Videotaping Protocol	3,230	1	2.5	8,075
6-Month Parent Services Follow-Up Interview	3,298	1	.75	2,474
Child Care Provider Interview	1,259	1	.50	630
Child Care Provider Observation Protocol	1,259	1	2	2,518
Staff Questionnaire	170	1	.5	85
Estimated Total Annual Burden Hours: 13,782.				

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 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 Information Services, Division of Information Resource Management, 370 L'Enfant Promenade, S.W., Washington, D.C. 20047, Attn.: ACF Reports Clearance Officer. All requests should be identified by title.

In addition, requests for copies may be made and comments forwarded to the Reports Clearance Officer over the Internet by sending a message to rkatson@acf.dhhs.gov. Internet messages must be submitted as an ASCII file without special characters or encryption.

Comments are invited 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) ways to enhance 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.

Dated: March 28, 1996.

Roberta Katson,

Director, Division of Information Resource Management Services.

[FR Doc. 96–8203 Filed 4–3–96; 8:45 am]

BILLING CODE 4184–01–M

Food and Drug Administration

[Docket No. 96N–0089]

Establishment of Lists of U.S. Firms/Processors Exporting Shell Eggs, Dairy Products, Game Meat and Game Meat Products to the European Community; Request for Information From Such Firms

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it intends to establish lists of U.S. firms/processors exporting shell eggs, dairy products, game meat and game meat products to the European Community (EC) that manufacture products in compliance with U.S. food laws and regulations. FDA is taking this action in response to current changes in the EC legislation that will require countries trading with any of the EC member countries to provide lists of firms exporting certain animal derived commodities to the EC. FDA is requesting that U.S. firms presently exporting, or who anticipate exporting these commodities to the EC, provide the agency with information for inclusion on the appropriate list. This list will be updated on a quarterly basis and will be submitted to the EC. This notice is intended to alert all U.S. exporters to the EC requirement for lists of companies processing animal derived commodities that are exported to the EC member states. The agency is also requesting comments on the best mechanisms to be used in obtaining future changes and additions to the EC lists for these commodities.

DATES: Written comments and information for inclusion on the EC list by April 30, 1996. Written comments on the information collection requirements by May 6, 1996.

ADDRESSES: Submit written information for inclusion on the EC list to Marilyn F. Balmer, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, FAX 202–205–4422 or E-mail MFB@FDACF.SSW.DHHS.GOV.

Submit written comments on the best mechanisms to be used in obtaining future changes and additions to the EC lists for dairy products, shell eggs, game meat and game meat products to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. All comments should be identified with the Docket number found in brackets in the heading of this document.

Submit written comments on the information collection requirements to DHHS Reports Clearance Officer, Paperwork Reduction Project (0910–0320), Hubert Humphrey Bldg., 200 Independence Ave. SW., rm. 531–H, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Marilyn F. Balmer, Center for Food

Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4400.

SUPPLEMENTARY INFORMATION:

I. Introduction

The EC is a group of 15 European countries that have agreed to harmonize their commodity requirements to facilitate commerce among the member states. Those countries which are members of the EC are as follows: United Kingdom, France, Italy, Spain, Portugal, Germany, Netherlands, Belgium, Denmark, Luxembourg, Ireland, Greece, Austria, Finland, and Sweden.

Lists of processors (businesses) and the use of public and/or animal health certificates are an integral part of EC legislation on sanitary measures to protect public and animal health in the trade of live animals and animal products.

The Council of the EC has issued directives which contain the rules and procedures that must be followed by the member states for intracommunity trade in commodities. Member states of the EC are required by EC legislation to maintain lists of processing firms which meet these EC directives. The lists of processors approved by member states are published in the *Official Journal of the European Community*. Public and/or animal health certificates issued by the government of the country of origin are required to accompany every shipment of these products. For animal derived commodities, these directives were developed with regard to animal and public health considerations. Dates are being established at which time importation of commodities from third countries (i.e., the United States and other non-EC countries) will be subject to the minimum requirements of these directives. The Department of Agriculture and FDA are presently negotiating with the EC with a view to establishing agreement on the comparability of U.S. and EC regulatory systems to ensure that commodities trade with the EC is not disrupted. The EC directives on shell eggs, dairy products, game meat and game meat products are as follows:

1. EC Council Directive 92/46/EEC contains the rules for the production and sale of raw milk, heat-treated milk and milk-based products. In chapter III, article 23 of this directive, for importation into the EC from third countries, lists and certificates are required. The list identifies the establishments which meet the EC requirements and the certificates are health certificates (animal and public).

2. EC Council Directive 92/45/EEC contains the rules for slaughter and sale of wild-game meat. In chapter III, articles 16 and 17 of this directive, for importation into the EC from third countries (non-EC) lists and certificates are required. The list identifies establishments which meet EC requirements and the certificates are both public and animal health certificates.

3. EC Council Directive 91/495/EEC contains the rules for the production, slaughter, and sale of rabbit meat and farmed-game meat. EC Council Directive 92/118/EEC, annex 1, chapter 11 requires that for imported rabbit meat and farmed game meat that animal and public health certificates be provided and that chapters II and III from Directive 91/495/EEC be followed. Directive 91/495/EEC requires lists of establishments which meet the requirements.

4. EC Council Directive 92/5/EEC contains the rules for the production and marketing of meat products including those derived from game meats. EC Council Directive 92/118/EEC, annex II, chapter 1 requires that imported meat products have a public health certificate and that rules from Directive 77/99/EEC, which was amended by Directive 92/5/EEC be followed. Within these directives lists of establishments are required. Meat products are those prepared from or with meat which has undergone treatment such that the cut surface no longer has the characteristics of fresh meat.

5. EC Council Directive 94/65/EC contains the rules for production and marketing of meat preparations. Meat preparations include those products derived from game meat. The EC directive further distinguishes these products by specifying that the cut surface of the meat preparations has not lost the characteristics of fresh meat. In chapter V, article 13, certificates and lists are required for importation of these products from third countries (non-EC).

6. EC Council Decision 94/371/EEC, Council Regulation EEC N 1907 and Commission Regulation EEC N 1274/91 contains the rules for the production and marketing of shell eggs. Council Directive 92/118 lays down the animal and public health requirements for trade and imports not subject to specific EC rules. Within these directives lists and certificates are required.

Shell eggs, hard cooked eggs and imitation egg products; dairy products; and game meats and game meat products (i.e., non-FSIS mandatorily inspected meat and poultry) are commodities for which the FDA is the Federal agency responsible for public health protection. Other governmental agencies such as Agriculture Marketing Service and Food Safety Inspection Service offer voluntary inspection of these commodities.

II. Intention to Establish Lists of U.S. Firms/Processors

Initially, FDA intends to establish lists of U.S. firms/processors that meet U.S. regulations and export to the EC the following products: Shell egg, dairy products and game meat commodities. Inclusion of U.S. firms/processors on these lists is voluntary. However, commodities from firms not on these lists could be detained at the EC port of entry. In the past, seafood shipments from firms not on the seafood list were detained and not allowed into the EC. FDA officials accompanied by EC officials may visit any firm placed on these lists for auditing of the U.S. public and animal health systems.

U.S. firms/processors that export the previously mentioned products to the EC and want to be included in the appropriate lists that the agency is developing should submit the following information to FDA to Marilyn F. Balmer (address above):

1. Business name and address;

2. Name and telephone number of contact person;

3. List of products presently shipped to EC and those intended to be shipped in the next 2 years;

4. Name and address of the manufacturing plant for each product;

5. 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.

The mechanism for updating and maintaining these lists is being reviewed. Comments on methods for maintenance are welcome.

FDA is presently considering procedures for certificates and will notify exporters in an appropriate manner.

III. Paperwork Reduction Act

OMB has approved this collection of information under the emergency processing provision of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(j)) and has assigned OMB control number 0910–0320. Public reporting burden for this voluntary collection of information is estimated to average 0.25 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and

completing the collection of information. Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing the burden, to: DHHS Reports Clearance Officer, Paperwork Reduction Project (0910–0320), Hubert Humphrey Bldg., 200 Independence Ave. SW., rm 531–H, Washington, DC 20201. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a current valid OMB control number.

Submit written information for inclusion on the EC list to Marilyn F. Balmer (address above).

Submit written comments on the best mechanisms to be used in obtaining future changes and additions to the EC lists for dairy products, shell eggs, game meat and game meat products to the Dockets Management Branch (address above). All comments should be identified with the docket number found in the brackets in the heading of this document.

Dated: March 29, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–8360 Filed 4–1–96; 3:24 pm]

BILLING CODE 4160–01–F

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meeting and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1–800–741–8138 or 301–443–0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETING: The following advisory committee meeting is announced:

–Nonprescription Drugs Advisory Committee With Representation From the Drug Abuse Advisory Committee

–Date, time, and place. April 19, 1996, 8:30 a.m., Holiday Inn—Silver Spring, Grand Ballroom, 8777 Georgia Ave., Silver Spring, MD.

–Type of meeting and contact person. Open public hearing, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 11:30 a.m.; closed presentation of data, 11:30 a.m. to 12 m.; open committee discussion, 12 m. to 3 p.m.; closed presentation of data, 3 p.m. to 3:30 p.m.; open committee discussion, 3:30 p.m. to 5 p.m.; Kennerly K. Chapman, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or Liz Ortuzar (address above), 301–443–4695, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Nonprescription Drugs Advisory Committee, code 12541 or the Drug Abuse Advisory Committee, code 12535.

General function of the committees. The Nonprescription Drugs Advisory Committee reviews and evaluates available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products for use in the treatment of a broad spectrum of human symptoms and diseases. The Drug Abuse Advisory Committee advises on the scientific and medical evaluation of information gathered by the Department of Health and Human Services and the Department of Justice on the safety, efficacy, and abuse potential of drugs and recommends actions to be taken on the marketing, investigation, and control of such drugs.

–Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before April 5, 1996, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

–Open committee discussion. The committee will discuss new drug application (NDA) 20–536, Nicotrol® (nicotine transdermal system, Pharmacia Upjohn/McNeil Consumer Products) indicated as an aid to smoking cessation for the relief of nicotine withdrawal symptoms, to switch from prescription to over-the-counter status; and supplemental NDA 20–165/S–011 Nicoderm® (nicotine patch, Hoescht Marion Roussel/Alza Corp.), indicated as an aid to smoking cessation for the relief of nicotine withdrawal symptoms, to switch from prescription to over-the-counter status.

–Closed presentation of data. The committee will hear trade secret and/or confidential commercial information. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).––

Each public advisory committee meeting listed above may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. The dates and times reserved for the separate portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this Federal Register notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral