and thereby indirectly acquire additional voting shares of Spur Security Bank, Spur, Texas.

Board of Governors of the Federal Reserve System, December 14, 2000.

Robert deV. Frierson, Associate Secretary of the Board. [FR Doc. 00-32357 Filed 12-19-00; 8:45 am] BILLING CODE 6210-01-S

FEDERAL TRADE COMMISSION

[File No. 001 015; Docket No. C-3989]

America Online, Inc., and Time Warner Inc.; Analysis 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 that accompanies the consent agreement 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 January 16, 2001.

ADDRESSES: Comments should be directed to: FTC/Office of the Secretary, Room H–159, 600 Pennsylvania Avenue, NW., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Richard Parker, FTC/H-374, 600 Pennsylvania Avenue, NW., Washington, DC 20580. (202) 326-2574. SUPPLEMENTARY INFORMATION: Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46, and section 2.34 of the Commission's 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 December 14, 2000), on the World Wide Web, at http://www.ftc.gov/os/2000/12/ index.htm A paper copy can be obtained from the FTC Public Reference Room, Room H-130, 600 Pennsylvania Avenue, NW., Washington, DC 20580,

either in person or by calling (202) 326-3627

Public comment is invited. Comments should be directed to: FTC/Office of the Secretary, Room H-159, 600 Pennsylvania Avenue, NW., Washington, DC 20580. Two paper copies of each comment should be filed, and should be accompanied, if possible, by a 3¹/₂ inch diskette containing an electronic copy of the comment. Such comments or views will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with section 4.9(b)(6)(ii) of the Commission's Rules of Practice (16 CFR 4.9(b)(6)(ii)).

Analysis of Proposed Consent Order To Aid Public Comment

I. Introduction

The Federal Trade Commission ("Commission") has accepted for public comment from America Online, Inc. ("AOL") and Time Warner Inc. (Time Warner") (collectively "Proposed Respondents") an Agreement Containing Consent Orders ("Proposed Consent Agreement"), including the Decision and Order ("Proposed Order"). The Proposed Respondents have also reviewed a draft complaint. The Commission has now issued the complaint and an Order to Hold Separate ("Hold Separate Order"). The Proposed Consent Agreement intends to remedy the likely anticompetitive effects arising from the merger of AOL and Time Warner.

II. The Parties and the Transaction

AOL is the world's leading internet service provider ("ISP"), providing access to the internet for consumers and businesses. AOL operates two ISPs: America Online, with more than 25 million members; and CompuServe, with more than 2.8 million members. AOL also owns several leading Internet products including AOL Instant Messenger, ICQ, Digital City, MapQuest, and MoviePhone; the AOL.com and Netscape.com portals; the Netscape 6, Netscape Navigator and Communicator browsers; and Spinner.com and NullSoft's Winamp, leaders in Internet music.

Time Warner is the nation's second largest cable television distributor, and one of the leading cable television network providers. Time Warner's cable systems pass approximately 20.9 million homes and serve approximately 12.6 million cable television subscribers, or approximately 20% of U.S. cable television households. Time Warner, or its principally owned subsidiaries, owns leading cable

television networks, such as HBO, Cinemax, CNN, TNT, TBS Superstation, Turner Classic Movies and Cartoon Network.

Time Warner also owns, directly or through affiliated businesses, a wide conglomeration of entertainment or media businesses. Time Warner's holdings include leading magazine franchises, such as Time, People and Sports Illustrated; copyrighted music from many of the world's leading recording artists that it produces and distributes through a family of established record labels, such as Warner Bros. Records. Atlantic Records. Elektra Entertainment and Warner Music International; the unique and extensive film and animation libraries owned or managed by Warner Bros. and New Line Cinema; and trademarks, such as the Loonev Tunes characters, Batman and The Flintstones; the WB Network, a national broadcasting network; and Internet websites, such as CNN.com. Time Warner is the majority owner of Road Runner (the trade name of ServiceCo, LLC), the second largest provider of cable broadband ISP service in the U.S., serving more than 1.1 million subscribers. Road Runner has an exclusive contract to provide cable broadband ISP service via Time Warner's cable systems through December 2001.

On January 10, 2000, AOL and Time Warner entered into an Agreement and Plan of Merger (the "merger"), pursuant to which Time Warner common stockholders will receive 1.5 shares of the combined AOL Time Warner ("combined company," or "AOL Time Warner") for each share of Time Warner common stock they hold. AOL common stockholders will receive one share of common stock of AOL Time Warner for each share of AOL common stock they hold.

III. The Proposed Complaint

According to the complaint the Commission intends to issue, AOL's merger with Time Warner will have anticompetitive effects in three relevant product markets: (1) The market for broadband Internet access; (2) the market for residential broadband Internet transport services, or last mile access; and (3) the market for interactive television ("ITV") services.

AOL is the dominant narrowband ISP. Its narrowband customer base positions AOL to become a significant broadband ISP competitor as well. Time Warner provides broadband Internet access through Road Runner, a partially owned subsidiary in which it has a controlling interest. AOL and Road Runner are two of the most significant broadband ISP

competitors in Time Warner cable areas. According to the Commission's draft complaint, the relevant broadband ISP markets are or are likely to become highly concentrated as a result of the merger, and the merger will increase the ability of the combined firm to unilaterly exercise market power in Time Warner cable areas and throughout the United States. Moreover, new entry is not likely to be timely or sufficient to prevent the combined firm from exercising market power.

In the market for broadband Internet transports services, the Commission's complaint alleges that cable television lines and digital subscriber lines ("DSL") are the two principal means of providing last mile access for broadband ISPs to the customers. Satellite and fixed wireless technologies also provide last mile access, but consumers do not view them as viable alternatives for DSL or cable broadband access. Currently, AOL's principal means of providing broadband access to its subscribers is through DSL, and every broadband subscriber it signs represents a lost revenue opportunity for cable broadband providers. AOL's merger with Time Warner will reduce its incentives to promote and market broadband access through DSL in Time Warner cable areas, adversely affecting DSL rollout in those areas and nationally, and will increase AOL Time Warner's ability to exercise unilateral market power in those areas.

According to the Commission's complaint, ITV combines television programming with Internet functionality. Cable television lines have distinct competitive advantages over DSL in providing ITV services to broadband customers. AOL recently launched AOL TV, a first generation ITV service, and is well positioned to become the leading ITV provider. Local cable companies will play the key role in enabling the delivery of ITV services. After the merger, AOL Time Warner will have incentives to prevent or deter rival ITV providers from competing with AOL's ITV service. Thus, the merger could enable AOL to exercise unilateral market power in the market for ITV services in Time Warner cable areas, which also affects the ability of ITV providers to compete nationally.

IV. Terms of the Proposed Order

The Proposed Order is effective for a term of five years and resolves the Commission's antitrust concerns with the merger as discussed below.

A. Broadband Internet Access Services

Under the terms of the Proposed Order, before Time Warner can make AOL's broadband ISP service available in certain identified cable divisions representing over 70 percent of Time Warner's cable customers ("Identified Cable Divisions"),¹ Time Warner must first make available cable broadband service offered by Earthlink, Inc. pursuant to an agreement between Time Warner and Earthlink that the Commission has evaluated and approved.

In addition, Respondents cannot begin to advertise or promote AOL's broadband ISP service to subscribers in a cable division until Earthlink's competing ISP service is available to subscribers in that cable division or Earthlink advertises or promotes its service in that cable division, whichever occurs first. These provisions ensure that a competing ISP service, which is not affiliated with AOL Time Warner, is available to subscribers in most Time Warner cable areas at the same time that AOL introduces its cable broadband ISP service. It does not prevent Time Warner from conducting tests involving a limited number of subscribers that are purely for technological and operational implementation purposes, rather than for commercial purposes.

Within 90 days of making AOL's broadband ISP service available to subscribers, Time Warner must enter into agreements to carry at least two other non-affiliated broadband ISPs to provide cable broadband ISP services in the Identified Cable Divisions. The nonaffiliated ISPs, and Time Warner's agreements with them, must receive the prior approval of the Commission. If Time Warner fails to enter into such agreements within this time period, the Commission may appoint a trustee who will have the authority to enter into such agreements on Time Warner's behalf. These agreements must also receive the prior approval of the Commission. These agreements must be on terms comparable to either the Earthlink agreement, or any agreement between AOL and another cable system to provide AOL's cable broadband ISP service over that cable system.²

In Time Warner's other cable divisions, Time Warner must enter into cable broadband ISP service agreements that have received the prior approval of

the Commission with at least three other non-affiliated ISPs that have received the prior approval of the Commission within 90 days of making AOL's cable broadband ISP service available in each such division. If Time Warner fails to enter into such agreements within this time period, the Commission may appoint a trustee who will have the authority to enter into such agreements, which will be subject to the prior approval of the Commission. These agreements must be on terms comparable to either another alternative cable broadband ISP service agreement between a broadband ISP and the Proposed Respondents approved by the Commission, or any agreement between AOL and another cable system to provide AOL's cable broadband ISP service over that cable company's system.

The Proposed Order requires Time Warner to include several provisions in the agreements it negotiates with the non-affiliated ISPs. Specifically:

 Time Warner must include a most favored nation ("MFN") clause in all alternative cable broadband ISP service agreements submitted to the Commission for approval. The MFN must provide that if AOL executes a cable broadband ISP service agreement with another cable system operator, Respondents must provide a copy of the agreement with that cable system operator to a Monitor Trustee appointed by the Commission; give notice of the execution of the agreement to each nonaffiliated ISPs that is a party to an alternative cable broadband ISP service agreement approved by the Commission; and give the non-affiliated ISPs the ability to convert to all of the rates and terms in the cable system operator's agreement;

• Time Warner must also include in all alternative cable broadband ISP service agreements submitted to the Commission for approval a requirement that if Proposed Respondents makes available different levels of service to their affiliated ISPs, they must make those levels of service available to nonaffiliated ISPs;

• Time Warner must also include in all alternative cable broadband ISP service agreements submitted to the Commission for approval a requirement that if Proposed Respondents make available any network flow monitoring data or usage accounting to any of their affiliated ISPs, they must make that same data or accounting available to non-affiliated ISPs;

• Time Warner must also include in all alternative cable broadband ISP service agreements, at the option of the non-affiliated ISP, a requirement that

¹ The identified cable divisions to which this provision applies are: New York City, Tampa Bay, Central Florida, Houston, Raleigh/Fayettevile, Western Ohio, Northern Ohio, Charlotte, Los Angeles, Milwaukee, Greensboro, Hawaii, Cincinnati, San Antonio, Syracuse, Kansas City, South Carolina, Columbus, Rochester, Albany, and any other cable division with 300,000 subscribers or more that is controlled by Respondents.

² This provision applies to the following cable systems: Adelphia, AT&T, Cablevision, Charter, Comcast, and Cox.

disputes concerning compliance with the rates, terms, and conditions of that agreement shall be submitted to binding arbitration; and

• If requested by a non-affiliated ISP, Time Warner must provide the nonaffiliated ISPs with the same point of connection within Time Warner's cable divisions that Time Warner provides to affiliated ISPs. This provision is intended to ensure that Time Warner may not discriminate against non-affiliated ISPs by providing them with a less-advantageous connection point to its network than it provides to AOL.

If any of the alternative cable broadband ISP service agreements approved by the Commission is for a term that terminates prior to expiration of the Proposed Order (*i.e.*, five years from the date the Proposed Order becomes final), the Proposed Order requires Time Warner to enter into an additional alternative cable broadband ISP service agreement with a nonaffiliated ISP, subject to the Commission's approval, that must take effect immediately upon the expiration of the original agreement. If the original alternative cable broadband ISP service agreement is for a term of at least three years, Time Warner must offer the nonaffiliated ISP that is a party to that agreement an option to renew the agreement for at least two years.

If Time Warner terminates any of the alternative cable broadband ISP service agreements approved by the Commission before the expiration of the Proposed Order, the Proposed Order requires Time Warner to enter into an additional alternative cable broadband ISP service agreement with a nonaffiliated ISP, subject to the Commission's approval, which must take effect immediately upon the expiration of the original agreement.

If any non-affiliated ISP terminates its alternative cable broadband ISP service agreement approved by the Commission before the expiration of the Proposed Order, or if the non-affiliated ISP ceases to make its ISP service available to subscribers in a particular identified cable division, Time Warner must enter into an additional alternative cable broadband ISP service agreement with a non-affiliated ISP, subject to the Commission's approval, within 90 days after the original non-affiliated cable broadband ISP service is no longer available to subscribers.

In addition to the broadband ISP service agreements described above, the Proposed Order also requires Time Warner to negotiate and enter into arms' length, commercial agreements with any other non-affiliated ISP that seeks to

provide cable broadband ISP service on Time Warner's cable system. Time Warner may decline to enter into such negotiations or agreements or impose rates, terms, or conditions based on cable broadband capacity constraints, other cable broadband technical limitations, or cable broadband business considerations, but only so long as it makes such determinations without discrimination on the basis of affiliation and not on the basis of the impact on Proposed Respondents' ISPs (including, but not limited to a decrease in subscribers of Proposed Respondents' ISPs).

The purpose of these provisions is to ensure that a full range of content and services from non-affiliated ISPs is available to subscribers; prevent discrimination by Proposed Respondents as to non-affiliated ISPs on the basis of affiliation, which would interfere with the ability of the nonaffiliated ISP to provide a full range of content and services; and remedy the lessening of competition in the market for broadband ISP service as alleged in the Commission's complaint.

B. Interactive Television and Other Internet Services

Section III of the Proposed Order prohibits Time Warner from interfering in any way with content passed along the bandwidth contracted for and being used by non-affiliated ISPs in compliance with their agreements with Proposed Respondents. The Proposed Order also prohibits Time Warner from discriminating on the basis of affiliation in the transmission or modification of content that Time Warner has contracted to deliver to subscribers over its cable systems. The Proposed Order specifically prohibits Time Warner from interfering with the ability to a subscriber to use, in conjunction with ITV services provided by a nonaffiliated entity, interactive signals. triggers, or other content that the Proposed Respondents have agreed to carry. If Time Warner has agreed to transmit ITV signals or interactive triggers that AOL subscribers can use, it cannot block transmission of such ITV signals or triggers to subscribers using a competing ITV service. In addition, the Proposed Order prohibits the Proposed Respondents from entering into any agreement with any other cable system that would interfere with the ability of the other cable system to enter into agreements with non-affiliated ISPs or ITV providers.

The Proposed Order also requires the Proposed Respondents to provide the Commission with all complaints from any non-affiliated broadband ISP relating to the failure of the Proposed Respondents to make content available. The Proposed Order also requires the Proposed Respondents to notify the Commission whenever a television programmer complains that the Proposed Respondents have failed to carry interactive triggers, signals or content through its cable systems.

C. Broadband Transport Services

Section IV of the Proposed Order requires AOL to charge the same or comparable price for its DSL service to subscribers in Time Warner cable areas where AOL cable broadband ISP service or Road Runner is available as AOL charges for its DSL service in areas in which neither AOL cable broadband ISP service nor Road Runner is available. However, AOL may charge different prices for its DSL service to the extent such pricing differences reflect any actual cost differences for DSL transmission services. The Proposed Respondents must include a description of these cost differences in the reports they are required to submit to the Commission.

The Proposed Order also requires AOL to market and promote its DSL services to subscribers in Time Warner cable areas where AOL cable broadband ISP service or Road Runner is available at the same or comparable level and in the same or comparable manner as it markets and promotes DSL services to subscribers in areas in which neither AOL cable broadband ISP service nor Road Runner is available.

D. Monitor Trustee Provisions

The Proposed Consent Order authorizes the Commission to appoint a Monitor Trustee to monitor compliance with the Order at any time after the Proposed Respondents sign the Consent Agreement. The Proposed Consent Order provides the Monitor Trustee with the power and authority to monitor the Proposed Respondents' compliance with the terms of the Proposed Consent Order, and full and complete access to personnel, books, records, documents, and facilities of the Proposed Respondents to fulfill that responsibility. In addition, the Monitor Trustee may request any other relevant information that relate to the Proposed Respondents' obligations under the Proposed Consent Order. The Proposed Consent Order precludes Proposed Respondents from taking any action to interfere with or impede the Monitor Trustee's ability to perform his or her responsibilities or to monitor compliance with the Proposed Consent Order.

The Monitor Trustee may hire such consultants, accountants, attorneys, and other assistants as are reasonably necessary to carry out the monitor Trustee's duties and responsibilities. The Proposed Consent Order requires the Proposed Respondents to bear the cost and expense of hiring these assistants.

E. Trustee Provisions

The Proposed Consent Order provides that the Commission may appoint a trustee to enter into broadband agreements with non-affiliated ISPs in two instances. First, if the Proposed Respondents have failed to enter into agreements with two additional ISPs in the Identified Cable Divisions within 90 days of making an affiliated ISP available to subscribers, the Commission may appoint a trustee to enter into an agreements, subject to the prior approval of the Commission. The trustee shall, for an additional 90 days, offer to enter into agreements with nonaffiliated ISPs that are comparable, taken as a whole, to (1) the Earthlink agreement; or (2) any broadband agreement AOL enters into with any other cable system operator. The trustee's obligation is to ensure that at least two non-affiliated ISPs are available on the Time Warner system in these divisions in addition to Earthlink.

The Commission may also appoint a trustee to enter into agreements in other time Warner cable divisions if the Proposed Respondents fail to enter into agreements with at least three nonaffiliated ISPs that the Commission approves within 90 days of making any affiliated ISP available. The trustee shall, for an additional 90 days, offer to enter into agreements with nonaffiliated ISPs that are comparable, taken as a whole, to (1) any other broadband agreement with a nonaffiliated ISP for carriage on any Time Warner cable system; or (2) any broadband agreement AOL enters into with any other cable system operator. The trustee's obligation is to ensure that at least three non-affiliated ISPs are available on the Time Warner cable systems in these divisions.

F. Order to Hold Separate

In addition to the Proposed Order, the Commission also issued an Order to Hold Separate ("Hold Separate Order"). The purpose of the Hold Separate Order is to prevent interim harm to competition and to prevent AOL from gaining a competitive first mover advantage through a relationship with Road Runner.

The Hold Separate Order requires the Proposed Respondents to hold AOL and

Road Runner separate in each Identified Cable Division until they have made an affiliated ISP available to broadband customers in that Identified Cable Division. The Hold Separate Order expressly prohibits AOL and Road Runner from, among other things, cross or joint promotional activities, joint or cooperative advertising, and any steps to benefit, directly or indirectly, from each other's business activities.

The Commission may appoint a trustee to monitor compliance with the terms of the Hold Separate Order.

V. Opportunity for Public Comment

The Proposed Consent Agreement has been placed on the public record for 30 days for receipt of comments by 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 or not to make the Proposed Order final.

By accepting the Proposed Agreement subject to final approval, the Commission anticipates that the competitive problems alleged in the complaint will be resolved. The purpose of this analysis is to invite public comment on the Proposed Consent Agreement, to aid the Commission in its determination of whether it should make final the Proposed Order contains in the agreement. This analysis is not intended to constitute an official interpretation of the Proposed Order, nor is it intended to modify the terms of the Proposed Order in any way.

By direction of the Commission. Donald S. Clark, Secretary.

corotary.

Concurring Statement of Commissioned Mozelle W. Thompson

The Commission voted today to accept the proposed consent in America On Line, Inc./Time Warner Inc., File Number 001-0105. This merger marks the first, and potentially most significant convergence of an Internet giant with a media, entertainment and cable conglomerate. Because it will form a broadband Internet powerhouse spanning the three market tiers of content, consumer interface, and broadband conduit, it may also shape the very contours of the market for high speed internet. In reviewing the merger, I have been concerned that without relief, the transaction would have threatened the significant open market environment that high technology and Internet companies, innovators, and consumers enjoy. I voted to accept the

settlement, however, because the consent will not only provide a means to address these concerns, but will also sent an important message to the market that high speed internet should continue to provide consumers with choice of service and diversity of content.

It is important to note that our remedy does give me pause for several reasons. First, the remedy—as some might observe—appears to be an unusually regulatory solution for a merger order. I generally prefer the divestiture of an ongoing business—*i.e.*, structural relief—to restore lost competition, a policy that the Commission has increasingly favored when settling merger cases.¹ Moreover, it is difficult to determine whether the order's five-year duration is too limited to accomplish the full goal of the relief.

Second, I am concerned that the Commission's open access relief might not preclude the possibility of harm from the merged entity's control of AOL and Time Warner content along with the Time Warner cable systems. The settlement nonetheless marks an important first step for future open competition on cable for Internet service providers and content providers. The relief provides that the Commission will supervise AOL Time Warner's conduct for five years; but it tells the market to continue to demand openness and competition in this important area. I note that the negotiated relief was improved from the companies' earliest proposals.

That being said, I also hope that the public does not over-interpret today's decision; despite the fact that this merger has been allowed to proceed without challenge, I expect that the Commission will scrutinize future Internet mergers as it does any mergeron a case-by-case basis. Moreover, the Commission will continue to exercise its antitrust responsibilities by taking appropriate action against anticompetitive behavior. Finally, though many interested parties will, no doubt, scrutinize the terms of the order ISP access agreements, these should not necessarily be seen as a template for future Internet access, but should instead be regarded as examples of how the public should share the benefits provided by the principles of Internet openness and diversity.

¹ In matters such as this, where the parties repeatedly failed to articulate how the merger would benefit consumers, I tend to believe structural relief—or outright challenge of the merger—is even more warranted to preserve the public interest.

For those reasons, I concur with accepting the proposed consent orders.

[FR Doc. 00–32394 Filed 12–19–00; 8:45 am] BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Agency Information Collection Activities: Proposed Collections; Comment Request

The Department of Health and Human Services, Office of the Secretary will periodically publish summaries of proposed information collection projects and solicit public comments in compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995. To request more information on the project or to obtain a copy of the information collection plans and instruments, call the OS Reports Clearance Officer on (202) 690– 6207.

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.

Proposed Projects 1. Federal Government-wide Automated Assurance and Institutional Review Board Registration System—NEW—The Office of Human Research Protection is proposing a Government-wide standardized, automated process for filing the assurance pertaining to the protection of human subjects in research, and for registering Institutional Review Boards (IRBs). **Respondents: Research Institutions;** Burden Information for the Assurance-Annual Number of Respondents: 1,334; Average Burden per Response: 2 hours; Total Annual Burden for Assurance: 2,668—Burden Information for IRB Registration—Annual Number of Respondents: 667; Average Burden per Response: 1 hour; Total Annual Burden for IRB Registration: 667 hours-Total Burden: 3335 hours.

Send comments to Cynthia Agens Bauer, OS Reports Clearance Officer, Room 503H, Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201. Written comments should be received within 60 days of this notice.

Dated: December 7, 2000.

Dennis P. Williams,

Deputy Assistant Secretary, Budget. [FR Doc. 00–32388 Filed 12–19–00; 8:45 am] BILLING CODE 4160–17–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Susceptibility of Foodborne Pathogens from Humans, Food, and Animals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Veterinary Medicine (CVM), announces that funds may be available to support an unsolicited grant application submitted by the Fundacion Mexicana para la Salud, Int. Hospital O'Horan, Merida, Yucatan, Mexico. The applicant has requested funds to study the epidemiology of Salmonella, Campylobacter and generic Escherichia coli in four states in Mexico to better define the susceptibility patterns of the pathogens and the risk factors associated with drug resistance, particularly quinolone resistance. FOR FURTHER INFORMATION CONTACT:

Regarding the administrative and financial management aspects of this notice: Peggy L. Jones, Division of Contracts and Procurement Management (HFA–520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301– 827–7160. Correspondence handcarried or commercially delivered should be addressed to 5630 Fishers Lane (HFA–520), rm. 2129, Rockville, MD 20857.

Regarding the programmatic aspects of this notice: David B. Batson, Office of Research (HFV–502), Center for Veterinary Medicine, Food and Drug Administration, 8401 Muirkirk Rd., Laurel, MD 20708, 301–827–8021.

SUPPLEMENTARY INFORMATION:

I. Objectives

The specific objectives of the proposed project are to: (1) Develop effective surveillance of antimicrobial resistance in foodborne pathogens in human, food, and veterinary laboratories at the four participating sites; (2) standardize the methods for

isolation, identification, and antimicrobial susceptibility testing of foodborne pathogens at these four sites; (3) determine the prevalence of Salmonella spp., Campylobacter spp., and quinolone-resistant generic E. coli in asymptomatic and ill humans, poultry, pork, beef, and healthy food animals on farms; (4) identify and compare susceptibility profiles of the Salmonella spp., Campylobacter spp., and generic E. coli isolates; and (5) assess the importance of direct and indirect contact with food-animals as risk factors for quinolone-resistance in these isolates.

II. Eligible Applicants

Assistance will only be provided to the Fundacion Mexicana para la Salud because of the following:

1. The Fundacion Mexicana para la Salud is the only organization that submitted an unsolicited application for the purpose stated above.

2. The project proposed by the applicant specifically addresses the National Antimicrobial Resistance Monitoring System objectives in general and international objectives for the establishment of an international data base.

3. The knowledge of sources of exposure to drug resistant pathogens in Mexico would provide information that could be made available to travelers and would also assist in making assessments of the levels of fluoroquinolone resistance in domestic cases of illness acquired from animal food products imported from Mexico and Guatemala.

4. An international data base can provide information to the international community on the level of antimicrobial drug resistance in foodborne pathogens, providing a means for assessing public health concerns.

5. The proposal would benefit CVM and the international community in the establishment of an international data base for antimicrobial susceptibility and enhance food safety activities globally.

III. Funding

We anticipate that approximately \$371,144, which is the requested level of funding, or some lesser amount will be made available in fiscal year (FY) 2001 to fund this project. It is expected that the award will begin sometime in FY 2001 and will be made for a 12month budget period within a project period of up to 3 years. Funding estimates may change. Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.