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E.O. 12356: DECL: OADR
 TAGS: EIND, ETRD, BR
 SUBJECT: EB ASSISTANT SECRETARY MCMINN'S MEETING WITH
 BRAZILIAN AMBASSADOR MOREIRA: PHARMACEUTICALS,
 4/16/87

REF: BRASILIA 4310

1. ~~CONFIDENTIAL~~ - ENTIRE TEXT.
2. SUMMARY. EB ASSISTANT SECRETARY MCMINN MET WITH BRAZILIAN AMBASSADOR MOREIRA AT THE LATTER'S REQUEST APRIL 16 TO DISCUSS THE IMPENDING PMA SECTION 301 PETITION ON PHARMACEUTICAL PATENT PROTECTION. MOREIRA OUTLINED SERIOUS GOB CONCERN OVER THE MOVE, STRESSING PROGRESS MADE ON NON-PATENT PHARMACEUTICAL ISSUES AND THE EFFECT A NEW 301 CASE COULD HAVE ON BILATERAL ECONOMIC RELATIONS. AS MCMINN STRESSED THE IMPORTANCE USG PLACES ON PROTECTION OF INTELLECTUAL PROPERTY RIGHTS AND THE

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NEED FOR GOB TO TAKE ACTION TO PROTECT PHARMACEUTICALS.
 MOREIRA OFFERED NO EVIDENCE THAT GOB IS CONSIDERING SUCH

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UNITED STATES DEPARTMENT OF STATE
 REVIEW AUTHORITY: NORMAN M. BOUTON
 DATE/CASE ID: 19 DEC 2001 200000143

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ACTION. END SUMMARY.

3. AMBASSADOR MOREIRA CALLED ON ASSISTANT SECRETARY MCMINN APRIL 16 TO DISCUSS THE PHARMACEUTICAL ISSUE AND PMA'S INTENT TO FILE A PETITION AGAINST BRAZIL UNDER SECTION 301 OF THE 1974 TRADE ACT. MOREIRA OPENED THE MEETING BY NOTING THAT HE HAD COME TO REEMPHASIZE GOB CONCERNS EXPRESSED DURING PAULO TARSO'S APRIL 15 MEETING WITH AMBASSADOR SHLAUDEMAN (REFTEL). HE ADDED THAT HE HAD OUTLINED GOB THINKING DURING A PHONE CALL EARLIER IN THE DAY TO DEPUTY USTR MICHAEL SMITH AND DURING A LUNCH WITH DEPUTY SECRETARY WHITEHEAD SEVERAL WEEKS EARLIER.

4. MOREIRA REFERRED TO BILATERAL CONSULTATIONS ON PHARMACEUTICAL ISSUES HELD IN NOVEMBER 1986 AND LAST MONTH. THE IMPENDING PMA 301 PETITION CONCERNS BRAZIL FOR THREE REASONS. FIRST, THE GOB IS AWARE OF INDUSTRY COMPLAINTS AND HAS TAKEN IMPORTANT STEPS TO IMPROVE THE SITUATION. SECOND, THE PETITION, WHICH PURPORTS TO ADDRESS AN UNFAIR TRADE PRACTICE, IS ITSELF UNFAIR SINCE BRAZIL HAS TAKEN POSITIVE ACTION. THIRD, A 301 PETITION WOULD COMPLICATE BILATERAL RELATIONS, GIVEN THE GENERAL ECONOMIC AND POLITICAL ENVIRONMENT, AT A TIME WHEN BRAZIL IS INVOLVED IN THE PROCESS OF WRITING A NEW CONSTITUTION.

5. MOREIRA OUTLINED GOB ACTIONS ON VARIOUS ASPECTS OF THE PHARMACEUTICAL ISSUE. ON MARKET RESERVE, PRESIDENT SARNEY HAS FIRMLY REJECTED ANY EXTENSION OF MARKET RESERVE TO PHARMACEUTICALS. ON PRICING, RECENT SIGNIFICANT PRICE INCREASES HAVE BEEN GRANTED TO THE INDUSTRY. THE GOB AIM, ACCORDING TO MOREIRA, IS TO ENSURE INDUSTRY PROFITABILITY WHILE AVOIDING

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HYPERINFLATION. PHARMACEUTICAL COMPANIES IN BRAZIL HAVE REACTED FAVORABLY.

6. REGARDING NEW DRUG REGISTRATION, MOREIRA SAID THAT PAST ABUSES AND ACCUSATIONS OF THE EXISTENCE OF EXPERIMENTAL AND WORTHLESS DRUGS ON THE BRAZILIAN MARKET HAD LED TO THE DEVELOPMENT OF OVEREXACTING, RIGOROUS CRITERIA FOR DRUG REGISTRATION. THE SITUATION HAD BECOME A REAL PROBLEM AND DRUG SHORTAGES HAD ARISEN. AS A RESULT, MOREIRA REPORTED THAT THE HEAD OF DIMED AND HER ENTIRE TEAM HAVE BEEN DISMISSED AND HAVE BEEN REPLACED

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WITH OFFICIALS WHO WILL TAKE A MORE PRAGMATIC (ALTHOUGH STILL RIGOROUS) APPROACH. HE UNDERLINED THE FACT THAT THIS MOVE INVOLVED SOME POLITICAL COSTS.

7. THE FINAL ISSUE, ACCORDING TO MOREIRA, INVOLVES PHARMACEUTICAL PATENTS. HE STATED THAT "PERHAPS WE NEED MORE TIME." HE ARGUED THAT FOREIGN PARTICIPATION IN THE BRAZILIAN PHARMACEUTICAL INDUSTRY HAD INCREASED IN THE PERIOD SINCE BRAZIL ELIMINATED PRODUCT AND PROCESS PATENTS. THE INDUSTRY HAS SURVIVED, EVEN PROSPERED, AND HAS LEARNED TO LIVE UNDER THE CURRENT SYSTEM.

8. MOREIRA STATED THAT THE GOB IS READY TO STUDY THE ISSUE, NOTING, HOWEVER, THAT THE GOVERNMENT COULD NOT ACT UNILATERALLY. THE ISSUE COULD BE DISCUSSED UNDER THE BROADER UMBRELLA OF URUGUAY ROUND TALKS ON INTELLECTUAL PROPERTY RIGHTS, OR PERHAPS IN THE CONTEXT OF AN AMENDMENT TO THE PARIS TREATY. HE POINTED OUT THAT A LOCAL INTELLECTUAL RIGHTS ADVOCACY GROUP WAS PREPARING TO PRESENT A DRAFT STUDY TO THE BRAZILIAN GOVERNMENT.

9. MOREIRA ARGUED THAT NONE OF BRAZIL'S PHARMACEUTICAL POLICIES AND PRACTICES INVOLVE DISCRIMINATION AGAINST FOREIGN FIRMS. HE POINTED AGAIN TO THE PREDOMINANT FOREIGN SHARE IN THE INDUSTRY.

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10. HE STATED THAT A 301 PETITION AT THE PRESENT TIME WOULD BE VERY DETRIMENTAL. IT WOULD INHIBIT BRAZILIAN EFFORTS TO IMPROVE INDUSTRY CONDITIONS AND WOULD BECOME A POLITICAL ISSUE AT A TIME OF INTENSE CONSTITUTIONAL ACTIVITY. MOREIRA WARNED THAT RESTRICTIONS COULD BE WRITTEN INTO THE CONSTITUTION WHICH WOULD BE VERY DIFFICULT TO REMOVE.

11. AS MCMINN POINTED OUT THAT THE PLANNED PMA PETITION IS A PRIVATE SECTOR INITIATIVE WHICH OUR TRADE LAW PERMITS. SHOULD THE PMA PROCEED, THE ADMINISTRATION WOULD FOLLOW THE NORMAL 301 PROCESS AS PRESCRIBED BY THE LAW.

12. AS MCMINN EMPHASIZED THAT INTELLECTUAL PROPERTY RIGHTS IS AN ISSUE WHICH HAS RECEIVED CONSIDERABLE

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ATTENTION WITHIN THE ADMINISTRATION. THE PHARMACEUTICAL PATENT ISSUE IN PARTICULAR HAS BEEN VERY VISIBLE, AND HAS BEEN FACTORED INTO U.S. POLICY INITIATIVES IN THE URUGUAY ROUND, THE U.S. GENERALIZED SYSTEM OF PREFERENCES, AND CONGRESSIONAL LEGISLATION. PROTECTION OF INTELLECTUAL PROPERTY RIGHTS IS A KEY ISSUE FOR BOTH DEVELOPING AND DEVELOPED COUNTRIES.

13. AS MCMINN DISCUSSED THE PMA'S PLANNED APRIL 21 FILING OF THE 301 PETITION. HE INFORMED MOREIRA THAT USTR WAS AWARE THAT DATE WAS A BRAZILIAN NATIONAL HOLIDAY AND HAD INFORMED PMA IN THE HOPES THAT A DIFFERENT DATE WOULD BE CHOSEN. (FYI. DEPARTMENT HAS SINCE LEARNED

THAT PMA PLANS TO FILE ITS PETITION ON APRIL 23. END FYI.)

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14. AS MCMINN STRESSED THAT IT WOULD BE MOST UNFORTUNATE TO HAVE A SITUATION IN WHICH WE COULD NOT SUCCESSFULLY RESOLVE THE PATENT ISSUE. THE PMA HAD PREVIOUSLY HELD OFF IN FILING A 301 PETITION, GIVEN ONGOING GOVERNMENT TO GOVERNMENT TALKS. HOWEVER, THE INDUSTRY IS NOW DECIDED, AND THE QUESTION IS OUT OF THE ADMINISTRATION'S HANDS. THE ISSUE IS NOT ONE WHICH CAN BE MASKED WITH CREATIVE LANGUAGE.

15. MOREIRA AGREED THAT THE TIMING WAS UNFORTUNATE, NOTING THAT THE DANGER EXISTED THAT A DISPUTE OVER PHARMACEUTICALS COULD SPILL OVER INTO OTHER AREAS. ANY ADDITIONAL TIME COULD BE IMPORTANT. MOREIRA CLAIMED THAT U.S. SUBSIDIARIES IN BRAZIL RECOGNIZED PROGRESS MADE TO DATE, AND DISAGREED WITH THEIR PARENT COMPANIES' DECISIONS TO PROCEED WITH A 301 PETITION AT THIS TIME. IN MOREIRA'S VIEW, THE EFFECT OF THE PETITION WOULD BE A WORSENING OF THE CURRENT SITUATION FOR THE PHARMACEUTICAL INDUSTRY IN BRAZIL.

16. COMMENT. THE BRAZILIANS ARE CLEARLY CONCERNED BY THE PROSPECTIVE 301 ACTION. MOREIRA IMPLIED THAT THE PMA PETITION COULD HAVE SERIOUS REPERCUSSIONS IN OTHER ASPECTS OF OUR BILATERAL ECONOMIC RELATIONS. ABSENT FROM HIS PRESENTATION, HOWEVER, WAS ANY INDICATION THAT BRAZIL

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IS PREPARED TO GIVE SERIOUS CONSIDERATION TO
PHARMACEUTICAL PATENT PROTECTION. END COMMENT.
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