Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than October 27, 1998.

A. Federal Reserve Bank of Atlanta (Lois Berthaume, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303-2713:

1. Community Financial Group, Inc., Nashville, Tennessee; to engage *de novo* through its subsidiary, American Growth Finance, Inc., Dallas, Texas, a *de novo* joint venture, and thereby engage in making, acquiring, and servicing loans or other extensions of credit, pursuant to § 225.28(b)(1) of Regulation Y.

Board of Governors of the Federal Reserve System, October 6, 1998.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 98–27332 Filed 10–9–98; 8:45 am]

BILLING CODE 6210–01–F

FEDERAL TRADE COMMISSION

Premerger Notification: Reporting and Waiting Period Requirements

AGENCY: Federal Trade Commission.

ACTION: Notice of adoption of formal interpretation and request for comments.

SUMMARY: The Premerger Notification Office (''PNO'') of the Federal Trade Commission (''FTC''), with the concurrence of the Assistant Attorney General in charge of the Antitrust Division of the Department of Justice (''DOJ''), is adopting a Formal Interpretation of the Hart-Scott-Rodino Act, which requires certain persons planning certain mergers, consolidations, or other acquisitions to report information about the proposed transactions to the FTC and DOJ. The Interpretation concerns the reportability of certain transactions involving a Limited Liability Company (''LLC''), a relatively new form of entity authorized by state statutes. Under the Interpretation, the formation of an LLC will be reportable if it will unite two or more pre-existing businesses under common control. Similarly, acquisitions of existing LLC membership interests will be reportable if they would have the effect of uniting two or more pre-existing businesses under common control.

DATES: The effective date is December 14, 1998. Comments must be submitted on or before November 12, 1998.

ADDRESSES: Send written comments to Joseph G. Krauss, Assistant Director for the Premerger Notification Office, Bureau of Competition, Room 301, Federal Trade Commission, Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Joseph G. Krauss, Assistant Director for the Premerger Notification Office, Bureau of Competition, Room 301, Federal Trade Commission, Washington, DC 20580. Telephone: (202) 326–2713. Thomas F. Hancock, Attorney, Premerger Notification Office, Bureau of Competition, Room 301, Federal Trade Commission, Washington, DC 20580. Telephone: (202) 326–2946.

SUPPLEMENTARY INFORMATION: The text of Formal Interpretation Number 15 is set out below:

Formal Interpretation Number 15

Formal Interpretation Pursuant to § 803.30 of the Premerger Notification Rules, 16 CFR 803.30, Concerning the Reporting Requirements for the Formation of Certain Limited Liability Companies (''LLCs'') and for Acquisitions of Membership Interests in Certain Existing LLCs.

This is a Formal Interpretation pursuant to § 803.30 of the Premerger Notification Rules (''the rules''), 16 CFR 803.30, and 801.2(d) of the rules, 16 CFR 801.2(d). The rules implement Section 7A of the Clayton Act, 15 U.S.C. 18a, which was added by sections 201 and 202 of the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (''the act'').

The act requires the parties to certain mergers, acquisitions, and other business combinations to file reports with the FTC and the DOJ and to wait a specified period of time before consummating the transaction. The purpose of the act and the rules is to ensure that such transactions receive meaningful scrutiny under the antitrust laws, with the possibility of an effective remedy for violations, prior to consummation.

The LLC[1] is a relatively new form of business organization which is neither a partnership nor a corporation but a hybrid legal entity which combines certain desirable features of both partnerships and corporations. Specifically, an LLC is taxed as a partnership but shields its members from liability as a corporation shields its shareholders. The first LLC statute was passed in 1977 by Wyoming[2] and a trickle of other states followed. The use of LLCs expanded significantly after 1988 when the Internal Revenue Service (''IRS'') concluded that an LLC organized under the Wyoming statute was taxable as a partnership.[3] By 1993 all 51 jurisdictions had LLC laws of one form or another.

When it first encountered these types of organizational structures, the PNO concluded that as ''companies'' LLCs are ''entities'' within the meaning of § 801.1(a)(2), 16 CFR 801.1(a)(2), and that, until it had more experience with them, the PNO would deem LLCs to be corporations. Initially, therefore, § 801.40 of the rules, 16 CFR 801.40, ''Formation of joint venture or other corporations,'' governed the formation of LLCs and an interest in an LLC was treated as a voting security for HSR purposes.

On further analysis, the PNO concluded that this initial approach was inadequate. LLCs at the time were primarily used as a vehicle for the creation of start-up businesses. The PNO's treatment of LLCs resulted in requiring HSR filings in a large number of transactions that did not raise antitrust concerns. Furthermore, the PNO determined that in most LLCs the interest held by the members of the LLC was more like a partnership interest than that of a voting security interest. Consequently, in 1994, the PNO began to informally advise parties that the treatment of LLCs' for reporting purposes would depend on a determination of whether the interest acquired in the LLC was more like a voting security interest or more like a partnership interest.[4]

This subsequent treatment of LLCs has not been completely satisfactory. The use of LLCs has changed from primarily being a vehicle for start-up enterprises to being used now more frequently to combine competing businesses under common control. Indeed, the Commission's litigation staff has investigated several transactions raising potential antitrust concerns involving the formation of LLCs. In these transactions, previously separate

[1] This Formal Interpretation applies only to the reportability of the formation of certain LLCs and of acquisitions of interests in certain existing LLCs. The position of the FTC staff on the status and treatment under the act of other non-corporate entities such as partnerships remains unchanged.

[2] *Wyo. Stat.* §§ 17–15–101 to –135 (Supp. 1989).

[3] Rev. Rul. 88–76, 1988–2 C.B. 360, 361.

[4] Specifically, the formation of an LLC was treated as potentially reportable only *if* the LLC had a group which functioned like a board of directors *and* the LLC ownership interest resulted in the holder appointing person(s) other than its employees, officers, or directors (or those of entities controlled by the holder or its ultimate parent entity) to that group. In such cases, the LLC interest was treated as a voting security interest. In all other instances, LLC interests were treated as partnership interests and the acquisition of these interests was not reportable (unless the acquiring person would hold 100 percent of the interests as a result of the acquisition).

businesses were combined under common control when they were contributed to a single, newly-formed LLC. Nevertheless, the creation of the LLC to combine competing businesses under common control was not reportable under the PNO's current treatment. The union of competing businesses under common control is of obvious potential antitrust concern. Since the current approach to LLCs has not been useful in requiring filings for those transactions that are the most likely to have anticompetitive effects, the PNO staff has decided to revise its approach to LLCs to be more consistent with the intent of the act.

This Formal Interpretation, therefore, changes the PNO's treatment of LLCs as follows: The formation of an LLC which brings two or more pre-existing separately controlled businesses under common control (*i.e.* an interest entitling one party to 50 percent of the profits of the LLC or 50 percent of the assets of the LLC upon dissolution) is now reportable if the HSR size-of-person and size-of-transaction requirements are met. The formation of all other LLCs will be treated like the formation of a partnership and their reportability will be determined according to the partnership rule. The current analysis used to determine whether an LLC interest acquired is more like a voting security or a partnership interest will no longer be used.

The combination of businesses into a new LLC under common control is the functional equivalent of a merger or consolidation. Such combinations, like other unions of businesses under common control, are subject to the act. § 801.2(d)(1)(i) of the rules, 16 CFR 801.2(d)(1)(i), states that ''[m]ergers and consolidations are transactions subject to the act * * *'' Although combinations of businesses in LLCs are not mergers or consolidations in the strictest sense because they do not involve corporations,[5] they are substantively similar. As it was originally promulgated in 1978, § 801.2(d)(1)(i), 16 CFR 801.2(d)(1)(i), stated that ''[a] merger, consolidation, or other transaction combining all or any part of the business of two or more persons shall be an acquisition subject to the act * * *'' (emphasis added).[6] A similar rationale has long been used to require filings for acquisitions of non-profit corporations which, like LLCs, do not issue voting securities.[7] Imposing a filing requirement on the parties to such transactions promotes the basic purpose of the act and the rules, namely, to give the antitrust enforcement agencies advance notice of, and an opportunity to oppose, transactions which may violate the antitrust laws.

Furthermore, when a person contributes a business to an LLC to be controlled by another, such transfer is the functional equivalent of an acquisition of the assets of that business and should be so treated for HSR purposes. Reportable acquisitions of non-profit corporations are also reported as asset acquisitions for the same reason. Consequently, assuming the size-of-person and size-of-transaction tests are met, contributors to combinations of businesses in LLCs should report as if they were acquiring the assets to be contributed to the LLC by the other contributor(s).

Although § 801.40 of the rules, 16 CFR 801.40, which governs the reporting of the formation of corporate joint ventures and other new corporations, is not directly applicable to combinations of businesses in LLCs because LLCs are not corporations and do not issue voting securities, the principles embodied in § 801.40—especially in § 801.40(c)—are applicable here. The value of the assets of the new LLC for size-of-person test purposes should be determined in accordance with § 801.40(c). Parties required to file should complete Item 5(d) of the Notification and Report Form for Certain Mergers and Acquisitions. Like a new corporation under § 802.41 of the rules, 16 CFR 802.41, the new LLC need not file notification (but each contributor who meets the size-of-person test may need to do so). Typically, there would be no acquired person filing, as in the case of the formation of corporate joint ventures. The waiting period will not begin until all parties required to file have filed and are in compliance (cf. § 803.10(a)(2) of the rules, 16 CFR 803.10(a)(2)).

A ''business'' is defined for purposes of this Interpretation the same as an ''operating unit'' for purposes of § 802.1(a) of the rules, 16 CFR 802.1(a), namely, ''* * * assets that are operated * * * as a business undertaking in a particular location or for particular products or services, even though those assets may not be organized as a separate legal entity.'' For purposes of this Formal Interpretation, the contribution to an LLC of an interest in intellectual property, such as a patent, a patent license, know-how, and so forth, which is exclusive against all parties including the grantor, is the contribution of a business, whether or not the intellectual property has generated any revenues.

This new treatment of LLCs also affects the reportability of the acquisition of membership interests in existing LLCs. The acquisition of existing membership interests will be potentially reportable in two situations. Any person which acquires (or, as a result of an acquisition, will hold) a controlling interest in an existing LLC (*i.e.* an interest entitling it to 50 percent of the profits or 50 percent of the assets upon dissolution) may be required to file because such a transaction may bring two or more separate businesses under common control. Whether a filing is necessary when a person acquires a controlling interest in an existing LLC would depend on whether the acquiring person also has a business and whether the size of person and size of transaction criteria of the act are met. In situations where the acquisition of a membership interest in an LLC does not result in the combination of existing businesses under common control, the acquisition of such membership interest will be treated like the acquisition of a partnership interest. If any person subsequently acquires (or, as a result of an acquisition, will hold) 100 percent of the interests in that LLC, and has not previously filed for and consummated the acquisition of control of that LLC, that person will then be deemed to be acquiring the assets of that LLC and so may be required to file at that time.

Some of the considerations for why the formation of certain LLCs (and the acquisition of certain LLC interests) should be reportable may apply equally well to partnerships. The formation of a partnership is not reportable;[8] the position of the PNO is that acquisitions of partnership interests which do not result in one person's holding 100

[5] See, *e.g.*, 19 W. Fletcher, *Cyclopedia of the Law of Private Corporations* § 3:141 (perm. ed.1994). Mergers and consolidations are defined as transactions in which all constituent corporations (in the case of consolidations) or all but one (in the case of mergers) lose their separate legal identities as part of the transaction. When two or more businesses are united in an LLC, they do not lose their legal identities in this sense, but they do cease to be separate and independent.

[6] 43 FR 33539, July 31, 1978. This language does not appear in the current version of § 801.2(d). In 1983, this provision was changed to clarify and change the treatment of mergers and consolidations under the rules and this particular wording was eliminated. There is no indication that this change was intended to narrow the scope of § 801.2(d), however. According to the Statement of Basis and Purpose to the 1983 changes, 48 FR 34430, July 29, 1983, the Commission sought to make clear that mergers and consolidations are treated as acquisitions of voting securities and to change § 801.2(d) to enable the parties to a merger to determine which is the acquiring person and which is the acquired person.

[7] See, *The Premerger Notification Practice Manual*, ABA, 1991 ed., Interp. #109.

[8] § 801.40, 16 CFR 801.40.

percent of the interests in a partnership is non-reportable. The PNO believes that the current treatment of partnerships should remain unchanged for the time being. The treatment of partnerships was originally adopted, in part, because of the difficulty of monitoring compliance with HSR reporting obligations since many partnerships can be formed informally or through implication in many typical business arrangements. Furthermore, there has been no suggestion that partnerships are being used in any greater frequency now to combine competing businesses. In addition, a change in treatment of partnerships would likely require filings in a large number of transactions that do not raise any antitrust concern. Consequently, any change in the treatment of partnerships at this time appears premature.

In 1987, when the Commission promulgated § 801.1(b)(1)(ii) of the rules which allows a partnership to be controlled by another entity, the Commission reiterated this position on the reportability of acquisitions of partnership interests. It stated, however, that it would reconsider this issue from time to time to see whether any revision in this position is appropriate. See 52 FR 20058, 20061 (May 29, 1987). Accordingly, in connection with the adoption of this Formal Interpretation, the PNO is asking for comments on whether partnerships should be treated the same as LLCs with regard to formation, acquisition, or both. The PNO may in the future change its treatment of partnerships based on the comments received.

The following examples are an integral part of this Formal Interpretation:

1. ''A'' and ''B'' both plan to contribute their widget businesses to a new LLC in which each will acquire a 50 percent interest. This acquisition would be reportable if the size-of-person and size-of-transaction tests are met using the analysis in § 801.40(c) of the rules.

2. In Example 1, above, the result would be the same if ''A'' and ''B'' each intended to transfer its widget business into its own LLC, LA and LB, and ''A'' planned to take a 50 percent interest in LB and ''B'' a 50 percent interest in LA. In each case, two businesses would be coming under common control. Note, however, that the result may be different if ''A'' and ''B'' each get a 49 percent interest in the other's LLC. There, two businesses are not being united under common control. However, if the Commission concluded that this technical lack of common control was being used as an avoidance device it would apply the act and rules to the substance of the transaction pursuant to § 801.90 of the rules, 16 CFR 801.90.

3. Suppose ''A'' will contribute its widget business and ''B'' will contribute cash for operating capital to a new LLC. This would not be reportable if ''A'' will be the only controlling person because it does not unite two or more businesses. If ''B'' is also to be a controlling person and is engaged in a business, it will be reportable by ''B.''

4. Suppose that ''A'' proposes to consolidate its widget business, which it has conducted in two subsidiaries and a division, into a newly-formed LLC in which it will hold a 60 percent membership interest. This would not be reportable because, although separate businesses are being combined, they were not under separate control prior to the transaction.

5. Suppose that in year 1 ''A'' and ''B'' each contributes its widget business to a newly-created LLC, that the transaction was deemed to be reportable, that filings were made and the waiting period observed. Then, in year 5, ''C'' proposes to acquire ''B's'' interest which constitutes a controlling interest in the LLC. Assume that ''C'' is engaged in a business or businesses. The acquisition by ''C'' is potentially reportable because it unites under common control the business of the LLC and ''C's'' businesses, which were separate.

6. Suppose ''A,'' ''B,'' and ''C'' form a new LLC in which ''A'' will have a 60 percent interest and ''B'' and ''C'' each will have 20 percent interests. ''A,'' a large, international pharmaceutical company, contributes $100 million in cash. ''B'' contributes licenses to several patents which it will also continue to use to manufacture various drugs. ''C'' will contribute licenses which are exclusive even against itself for several drugs which are still at the testing stage and which have never been marketed. ''A'' has a potential reporting obligation for the formation of this LLC. With a 60 percent interest, ''A'' will control the LLC and it has its own business. Since the licenses ''B'' will contribute are not exclusive as against it, they do not constitute a business. The licenses being contributed by ''C'' do constitute a business, however, even though they have not generated any revenue, and this business is being brought under the control of ''A'' with ''A'''s own business when the new LLC is formed.

7. Suppose ''A'' and ''B'' are both regional grocery store chains which do their data processing in-house. ''A's'' data processing unit does work only for ''A'' and ''B's'' only for ''B.'' ''A'' and ''B'' decide to contribute the assets used in their data processing operations to a new jointly-controlled LLC which will provide data processing services to ''A'' and ''B.'' Assume the size tests are met. This would not be reportable because the assets used to provide such management and administrative support services do not constitute businesses. Cf § 802.1(d)(4) of the rules and Examples 10 and 11, 16 CFR 802.1(d)(4). This would be the case even if the new LLC intends to begin offering data processing services to third parties, since this would be beginning a new business rather than uniting existing businesses. Note however, that the result would be different if ''A'' or ''B'' had used its equipment to provide data processing services to others prior to contributing it to the new LLC for then it would be an existing business. The result would also be different if ''A'' and ''B'' were engaged in manufacturing and the assets to be contributed to the new LLC were used in part of a manufacturing process.

* * * * *

Request for Comments

The Federal Trade Commission staff asks for comments on this Formal Interpretation and may further modify its approach to LLCs based on the comments it receives. The staff would particularly like Commenters to address the following two issues:

A. Burden

The staff has assumed that compliance with this Formal Interpretation would not be unduly burdensome on any party or class of parties. The staff requests comments on the issue of the burden of compliance. Commenters who believe that the Formal Interpretation does create a special burden by, for example, significantly increasing the number of filings should describe the burden in detail.

B. Partnerships

At the time of the promulgation of the so-called partnership control rule, 16 CFR 801.1(b)(1)(ii), in 1987, the Commission stated that it might at some time in the future re-visit the subject of partnerships to see if it might be appropriate to revise the staff position that acquisitions which do not confer on the acquiring person 100 percent of the interests in a partnership are not reportable. The Commission suggested that, instead, it might make the acquisition of control of a partnership reportable. See 52 FR 20058, 20061 (May 29, 1987). Is this an appropriate time to do this? More specifically, is there a reason why partnerships and LLCs should be treated the same? Are

partnerships, for example, also being used increasingly to combine existing businesses? What factors influence the choice of creating a partnership versus an LLC?

Donald S. Clark,

Secretary.

[FR Doc. 98–27355 Filed 10–9–98; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97E–0012]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Rimadyl 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 Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that animal drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6620.

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 animal 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 animal 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 Commissioner of Patents and Trademarks 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 an animal drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(4)(B).

FDA recently approved for marketing the animal drug product Rimadyl (carprofen). Rimadyl is indicated for the relief of pain and inflammation in dogs. Rimadyl was shown to be clinically effective for the relief of signs associated with osteoarthritis in dogs. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Rimadyl (U.S. Patent No. 4,264,500) from Pfizer Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated January 22, 1997, FDA advised the Patent and Trademark Office that this animal drug product had undergone a regulatory review period and that the approval of Rimadyl represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Rimadyl is 6,572 days. Of this time, 5,910 days occurred during the testing phase of the regulatory review period, 662 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(j)) became effective:* October 30, 1978. The applicant claims August 23, 1979, as the date the investigational new animal drug application (INAD) became effective. However, FDA records indicate that the date of FDA's letter assigning a number to the INAD was October 30, 1978, which is considered to be the effective date for the INAD.

2. *The date the application was initially submitted with respect to the animal drug product under section 512(b) of the act:* January 3, 1995. The applicant claims December 29, 1994, as the date the new animal drug application (NADA) for Rimadyl (NADA 141–053) was initially submitted. However, a review of FDA records reveals that the date of FDA's official acknowledgement letter assigning a number to NADA 141–053 was January 3, 1995, which is considered to be the initially submitted date for NADA 141–053.

3. *The date the application was approved:* October 25, 1996. FDA has verified the applicant's claim that NADA 141–053 was approved on October 25, 1996.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,095 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before December 14, 1998, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before April 12, 1999, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 28, 1998.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 98–27285 Filed 10–9–98; 8:45 am]

BILLING CODE 4160–01–F